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Does a pain management programme impact on patients quality of sleep?

Submission date	Recruitment status	[_] Prospectively registered
04/08/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/09/2010	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
18/12/2020	Signs and Symptoms	[_] Record updated in last year

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
N/A

Study information

Scientific Title
Cognitive behavioural pain management programmes: impact on sleep quality in patients with chronic pain

Study objectives
1. That a cognitive behavioural pain management pain management programme will have long term positive effects on subjective and objective sleep quality in patients with chronic pain by comparison with a control group
2. To investigate the relationship between objective and subjective sleep quality and physical and psychological outcome measures

Ethics approval required
Old ethics approval format

Ethics approval(s)
St James/Adelaide and Meath Hospitals Research Ethics Committee approved in October 2008

Study design
Clinically wait-list controlled trial

Primary study design
Interventional

Secondary study design
Non 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
Chronic non-malignant pain

Interventions
Cognitive Behavioural Pain Management Programme (CBT-PMP):
A multi-disciplinary CBT-PMP provides the patient with multiple therapies involving comprehensive rehabilitation in each of the specialised areas. The core multi-disciplinary team includes a pain management physician, an occupational therapist, a physiotherapist and a clinical psychologist. They identify and change unhelpful thoughts and beliefs, promote relaxation, and help to change habits that contribute to disability. The multi-disciplinary team focuses on specific achievable goals established between the individual therapist and the patient. Participants are advised to practice the skills they have learned both at home, and in other

environments, integrating them into their everyday lives in order to help them to manage their pain more effectively.

Participants will attend three days a week for four consecutive weeks (10 am - 4 pm). The programme includes daily two-hour group sessions with physiotherapy (stretching programme, core-stability strengthening programme, paced individual exercise on a range of gym equipment, and functional restoration), occupational therapy (improving occupational function and environmental adaptation), and clinical psychology (cognitive behavioural therapy, relaxation techniques). Weekly education sessions with the Pain consultant are also held.

Control group:
The control group were taken from the waiting list for the cognitive behavioural pain management programme.

Both arms of the trial were assessed at baseline; the intervention group were re-assessed on completion of the 4-week pain management programme and again 2 months later. The waiting list control group were reassessed after three months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Patients and controls will be assessed one week prior to the commencement of the CBT-PMP, 4 weeks later on completion of the CBT-PMP (or usual care), and two months later:
1. Sleep:
1.1. Objective: Patients will be instructed to wear the Actiwatch (AW4, CamTech, Cambridge, UK) for 7 days (24 hours a day)
1.2. Self-report: Pittsburgh Sleep diary (PghSD) for 7 days
2. Physical Function (objective): The Simmond's functional assessment battery of tests
3. Pain (self-report): Numerical rating scale for current pain, pain at worst/best in last 7 days
4. Psychosocial beliefs (self-report): Tampa Scale of Kinesophobia (fear of re-injury), Hospital Anxiety and Depression Questionnaire
5. Health-related Quality of Life and function (self-report): 36-item short form health survey (SF-36)

Secondary outcome measures
No secondary outcome measures

Overall study start date
02/02/2009

Completion date
22/05/2010

Eligibility

Key inclusion criteria

1. Patients aged over 18 years, either sex
2. Patients with a diagnosis of chronic pain (pain greater than 6 months)
3. Patients who fulfil the criteria for the Adelaide and Meath Hospitals incorporating the National Children's Hospital (AMNCH) cognitive behavioural pain management programme (CBT-PMP) as per the multidisciplinary team
4. Patients willing to take part in the study
5. Patients who are suffering from sleep disturbance due to pain as determined by the Pittsburgh Sleep Quality Index questionnaire (a score greater than 5 indicating sleep disturbance)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Patients under 18 years
2. Patients who do not have a diagnosis of pain greater than 6 months duration
3. Deemed unsuitable for the AMNCH CBT-PMP as per the multidisciplinary pain team
4. Unwilling to take part in the study
5. Do not suffer from sleep disturbance due to pain as determined by the Pittsburgh Sleep Quality Index questionnaire (a score greater than 5 indicating sleep disturbance)
6. Pregnancy

Date of first enrolment
02/02/2009

Date of final enrolment
22/05/2010

Locations

Countries of recruitment
Ireland

Study participating centre
School of Public Health, Physiotherapy and Population Science
Dublin

Ireland
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Sponsor information

Organisation
Pfizer Healthcare Ireland (PHI) (Ireland)

Sponsor details
9, Riverwalk
National Digital Park
Citywest Business Campus
Dublin
Ireland
24

Sponsor type
Industry

Website
http://www.pfizer.ie

ROR
https://ror.org/05y381977

Funder(s)

Funder type
Industry

Funder Name
Pfizer Healthcare Ireland (PHI) (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	10/01/2011	18/12/2020	Yes	No