

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

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<b>Registration date</b> 13/09/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 18/12/2020	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?
<a href="#">Protocol article</a>	protocol	10/01/2011	18/12/2020	Yes	No