

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

Submission date 04/08/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 13/09/2010	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 18/12/2020	Condition category Signs and Symptoms	☐ Individual participant data ☐ 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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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 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

Primary study design

Interventional

Study design

Clinically wait-list controlled trial

Study type(s)

Treatment

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(s)

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)

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

ROR

<https://ror.org/05y381977>

Funder(s)**Funder type**

Industry

Funder Name

Pfizer Healthcare Ireland (PHI) (Ireland)

Results and Publications

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