

Impact on quality of life of a nursing intervention programme for patients with chronic non-cancer pain

Submission date 02/09/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/09/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 15/09/2014	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Chronic pain that is not caused by cancer is a wide-spread health problem and one that is not well controlled. Nurses can play a vital role in pain management, using their specialist knowledge and adopting a holistic approach to help patients to best manage their pain. Improving the quality of life, reducing disability, accepting state of health, coping, and breaking the vicious circle of pain will be the areas that our care management programme will concentrate on. We want to look at to what extent a nurse-guided service is successful at managing patients chronic non-cancer pain and investigate its effects on a patients quality of life, the amount of pain killing drugs taken, the amount of pain felt and how depressed or anxious they feel. We also want to see if the treatment helps patients to cope with their condition and how satisfied they are with the programme.

Who can participate?

Patients registered with the chronic pain unit (part of the anaesthesiology service) at the Hospital Costa del Sol. These patients are referred for attention, from a medical specialist, due to the uncontrolled chronic pain suffered.

What does the study involve?

Initially, all participants are asked to fill in a series of questionnaires on health-related quality of life, feelings of depression and anxiety and the amount of pain they feel. A nurse assesses the patients current ability to manage and cope with their condition. They are all then randomly allocated into one of two groups. Those in group 1 (control group) receive the usual care given to the patients at the pain clinic. An anaesthetist gives each patient a clinical, psychological and social examination and makes a brief assessment based on questions about the pain suffered (its location, intensity, characteristics, onset and duration). Those in group 2 (the experimental group) receive the usual care and the new nursing care programme for people with chronic non-cancer pain. This programme consists of an individualised initial session, followed by six group sessions. Assessments based on questionnaires for participants in both groups are then performed at 12 and 24 weeks after the start of treatment.

What are the possible benefits and risks of participating?

The programme of a low-risk, psycho-educational nature. CALIDO-CR is a structured programme intended to equip participants with the tools needed to improve their quality of life in relation to the pain experienced, by making appropriate use of health services and improving accessibility via the liaison nurse at the pain treatment unit.

Where is the study run from?

The Hospital Costa del Sol. Marbella (Spain)

When is the study starting and how long is it expected to run for?

June 2014 to April 2016

Who is funding the study?

The Regional Health Ministry of Andalusia.(Spain).

Who is the main contact?

Angeles Morales-Fernandez
alaiamf@yahoo.es

Contact information

Type(s)

Scientific

Contact name

Miss Angeles Morales-Fernandez

Contact details

Autovía A-7 Km 187

Marbella

Spain

29603

+34 (0) 671 597 031

alaiamf@yahoo.es

Additional identifiers

Protocol serial number

PI-0158-2013

Study information

Scientific Title

Impact on quality of life of a nursing intervention programme for patients with chronic non-cancer pain: an open, randomised controlled parallel study

Acronym

CALIDO-CR

Study objectives

A nursing-guided, structured programme for persons with chronic non-cancer pain might substantially benefit their health-related quality of life, coping strategies, pharmacological management and state of mind

Ethics approval required

Old ethics approval format

Ethics approval(s)

CEI Costa del Sol, 28/10/2013, ref. 002_CS_0251

Study design

Open randomised parallel controlled study.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic non-cancer pain

Interventions

The control group will follow the usual procedure established for such patients at our pain treatment unit. An anaesthetist will ascertain the patients clinical background and conduct a clinical, psychological and social examination (at present, no clinimetric tool is used for this purpose, nor is any particular procedure established).

These patients will be addressed in parallel, with both usual care and the new nursing care programme for people with chronic non-cancer pain. This programme consists of an individualised initial session, followed by six group sessions. At 12 and 24 weeks after the start of treatment, telephone follow up contact will be made and the clinimetric tools again applied. The experimental group will take part in six group therapy sessions led by nurses, aimed at the acquisition of tools for the self-management of pain. a holistic approach in which the patient plays a proactive role in addressing the disease process. Improving the quality of life, reducing disability, achieving acceptance of health status, coping, and breaking the vicious circle of pain should be the prime objectives of our care management programme.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Level of health-related quality of life (SF -36) v1
2. Level of pain (VAS)

All measured at baseline, at 12 weeks and 24 weeks

Key secondary outcome(s)

1. Coping policy (Nurses clinical judgment / NOC 1302)
2. Level of anxiety (GAD 7)
3. Level of depression (PHQ 9)
4. Level of satisfaction

All measured at baseline, at 12 weeks and 24 weeks, other than measure 4, which is measured only at the end of the study

Completion date

01/04/2016

Eligibility

Key inclusion criteria

1. Patients aged 18-70 years
2. Knowledge and understanding of Spanish language
3. Patients voluntarily agree to participate in the programme and give their signed informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

70 years

Sex

All

Key exclusion criteria

1. Patients with psychiatric pathology and/or cognitive deterioration (in case of doubt, determined by a brief examination of mental state)
2. Patients with a cancer
3. Patients with a terminal pathology
4. Patients pending the resolution of legal processes related to accidents, occupational incapacity and/or recognition of incapacity

Date of first enrolment

01/06/2014

Date of final enrolment

01/04/2016

Locations

Countries of recruitment

Spain

Study participating centre

Autovía A-7 Km 187

Marbella

Spain

29603

Sponsor information

Organisation

Regional Health Ministry of Andalusia (Spain)

ROR

<https://ror.org/01jem9c82>

Funder(s)

Funder type

Government

Funder Name

Regional Health Ministry of Andalusia (Spain)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration