ISRCTN95299159 https://doi.org/10.1186/ISRCTN95299159

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

Registration date
15/09/2014

Overall study status
Completed

Last Edited
15/09/2014

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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-Fernadez

Contact details
Autovía A-7 Km 187
Marbella
Spain
29603
+34 (0) 671 597 031
alaiamf@yahoo.es

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format

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 measure
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

Secondary outcome measures
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

Overall study start date
01/06/2014

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
138 subjects in each study arm (276 in total). Total n = 318 subjects.

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)

Sponsor details
Avda. Américo Vespucio 5, Bloque 2, 2°Planta Izq.
Parque Científico y Tecnológico Cartuja 93
Sevilla
Spain
41092
+34 (0) 955 040 450
fundacion.progreso.salud@juntadeandalucia.es

Sponsor type
Government

Website
http://www.juntadeandalucia.es/fundacionprogresoysalud/components/contacto/

ROR
https://ror.org/01jem9c82

Funder(s)

Funder type
Government

Funder Name
Regional Health Ministry of Andalusia (Spain)

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