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Promoting a Self Care Approach for Managing Persistent Pain

Submission date	Recruitment status	[ ] Prospectively registered
29/09/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/09/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/09/2013	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
N0030170835

Study information

Scientific Title

Study objectives
The principle research question is to explore if patients readiness to adopt a self-management approach to managing their persistent pain can be influenced by the introduction of self care support approaches at initial stages of referral to a pain management service.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Signs and Symptoms: Pain

Interventions
This study will explore if the early promotion of self-care approaches in the management of persistent pain symptoms can influence patients readiness to self-manage their condition. The theoretical framework informing this research is the Governments systematic approach to care for people with long-term conditions (NHS Modernisation Agency 2004) with an overall aim to help provide care tailored to the individuals needs and reduce reliance on healthcare professionals and services. Patients referred to a District General Hospitals chronic pain management service (CPMS) with a diagnosis of non-malignant musculo-skeletal pain that has been on going for 3 months or more will be the focus for this study. Participants will be randomly allocated to one of two groups, consisting of a control and interventional group. The control group will receive no intervention while participants allocated to the interventional group attend a 6 week, 2.5 hours a week self-care programme also known as the Expert Patient

Programme (EPP); a lay led self-management programme. In addition, they will be offered early access to a routine transcutaneous electrical nerve stimulation (TENS) trial and the pain clinic help line for added symptom management and support.

The study will take measures of both groups at the start, after 4 months and then at 9 months, using a postal questionnaire. In addition focus groups and a functional test will take place at 4 months and 9 months. To reduce possible influences on participants behaviour, focus groups /functional test will not be held prior to the intervention; experience with EPP suggests the effect of participants interacting with each other could influence their behaviour and therefore the validity of findings. All participants will be asked to complete the postal questionnaire at the assessment points, while volunteers will be asked to take part in the focus groups and functional tests. The focus groups/functional testing will take place in the CPMS department at St Peters Hospital and participants will be involved in choosing the day and time for these to take place.

In order to study this area a prospective longitudinal research design involving a randomised control trial (RCT) has been chosen. The longitudinal design will allow changes in participants behaviour to be measured over time, and by involving an RCT this will provide the best evidence for measuring the effectiveness of the intervention. Measures have been chosen that gather data that will permit comparisons between the intervention and control group and this research design will combine both quantitative and qualitative methodologies in one study; a design known as triangulation. Triangulation design has been chosen as it is planned that the quantitative data (questionnaires & functional test) will give numerical information allowing comparisons between the two groups, while the qualitative data (focus groups) will permit fuller understanding of differences between the two groups.

Further details of the measures involved are:
1. Self-report questionnaire: designed to cover the following areas: capture age, gender, personal status, number of years educated, use of healthcare services (GP, A&E, inpatient stays) length of time experiencing pain, diagnosis
2. Pain Stage of Change Questionnaire (PSOCQ): Consisting of 20 questions, its development and initial validation is designed to assess an individuals readiness to adopt a self-management approach to their persistent pain conditions (routinely/currently used in the CPMS).
3. Chronic Pain Acceptance Questionnaire (CPAQ): Consisting of 30 questions.
4. Brief Pain Inventory (BPI): Consisting of 11 questions, it was developed as a quick and simple tool to measure pain intensity and extent of interference in the lives of those suffering from pain (routinely/currently used in the CPMS).
5. Functional test: Measures walking and standing to sitting tolerance (routinely/currently used in the CPMS).
6. Focus groups: These are a more natural setting than an interview and will involve informal discussion focused around the topic of self-management.

The study has been designed around two hypothesis:
A null hypothesis suggests there will be no difference between the interventional and control group. A null hypothesis is offered because testing for how much effect the intervention may have on participants readiness to take on a self-management approach cannot be clearly predicted.
An alternative hypothesis is offered as there are no previous studies available in this area to indicate outcomes. This suggests the control group will regress in their readiness to adopt a self-management approach to managing their pain symptoms. Offering an alternative hypothesis will enable a one-sided null hypothesis to be tested, allowing this study to recruit a smaller sample size without reducing the significance of the test.

Decisions relating to the null/alternative hypothesis and sample size have all been arrived at following discussion and advice from a statistician at the University of Surrey, European Institute of Health & Medical Sciences.

Action to consult concerned communities has been taken during the course of designing this research, consisting of informal consultations with patients, the Health Promotion Specialist (HPS) based in a local Primary Care Trust, all members of the CPMS and the CPMS manager and Deputy Chief Executive of the Trust. The HPS is also involved in recruiting and training EPP tutors, and has been closely involved in shaping the design of this research. Members of the CPMS and service manager have been consulted individually and during a team presentation given by the Chief Investigator/Principle Investigator; the Trusts Deputy Chief Executive /Director of Nursing is the Chief Investigator/Principle Investigators line manager and discussion and support with reference to this research has taken place.

The benefits of a self-care approach in the management of long-term conditions are well documented in literature with no report of adversities occurring. However, it is recognised that a self-management approach may not suit all patients, but there is considerable potential for improvement in patients well being through the adoption of a self-care approach, and this is felt to outweigh any inconvenience that may be caused by participants being asked to attend the self-management programme and focus groups. This study also has the potential to provide additional research evidence to promote EPP and successfully integrate the Governments vision of a self-management culture into the ethos of the National Health Service.

A broad timetable of 7 months (currently running) is planned for the development of the research protocol, discussion with concerned communities and gaining ethical approval. Recruiting participants, gathering data from questionnaires and focus groups is divided into 4 cohorts. This is to enable sufficient numbers of participants to be recruited while recognising that no more than twenty participants in each intervention group is recommended. The cohorts will overlap within a total period 14 months during which time data will be collected using the postal questionnaire, focus group and functional testing.

Each focus group will be led by the CI/PI and supported by a member of the CPMS. Discussions will be taped (with patient consent) and transcribed verbatim by a secretary from the CPMS ensuring confidentially; a copy will be available to participants on request. As the data is collected it will be entered onto computer statistical analysis packages and from this interim analysis planned. This will be followed by the writing up stage, which has been allocated 7 months. The final submission date to the University for the research thesis is August 2007. A paper will be submitted in September 2007 as part of the Doctorate in Clinical Practice, and is intended for publication.

Discussion with the HPS and Trust has occurred and agreed that for practical reasons the research study will be based in one central location. The location chosen is the pain management department based at St Peters Hospital. The department has a room suitable for group work, disabled access/facilities and parking.

Formal arrangements to feedback research results to research participants have not been arranged, but should participants request this the CI/PI will make arrangements, either on an individual or group basis. A summary of the research findings will be made available in a research report for all members of the Trust and accessible to participants. There is an expectation by the University and Trust to disseminate the research findings, which will include presentations and publications. The latter will be freely accessible for participants and it is envisaged most presentations will have open access.

Considerable thought has been given to researcher effects and bias. Inevitably, participants will be aware of being studied and this may affect their behaviour often referred to as reactive effect . This cannot be controlled nor can the researcher avoid giving all participants, irrespective of whether they are allocated to the control or interventional group, information on self-care approaches. Patients require this information in order that they have sufficient knowledge and understanding to give informed consent to participate in the study. The researcher is also aware that being known as a member of the CPMS may allow participants to ask and access information that would not normally have been available at this stage of care. However, the researcher recognises to withhold such information would be unethical and where possible arrangements with the individual will be made to see them in the pain clinic once they have completed the study when further discussion can occur.

The researcher is aware bias could occur when participants are allocated to the control or intervention group. Involving an RCT design and selecting participants using a computer random selection tool will reduce the possibility of bias at this stage. To detect bias that may occur from the researchers perspective when interpreting the meaning of the qualitative data gathered from the focus groups; analysis will be checked by two members the CPMS and a university colleague to ensure its interpretation can be justified and ensure objectivity and credibility in the findings.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary measure at 0, 4 and 9 months using the Pain Stage of Change Questionnaire is a shift from contemplative stages of change to an action stage of change in patients exposed to early self care approaches in the treatment and management of their persistent pain.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2005

Completion date
01/01/2007

Eligibility

Key inclusion criteria
1. Male or female
2. Aged 18-75
3. Experiencing continuous/intermittent non-malignant pain 3 months or longer referred to pain management service at Ashford and St Peter's Hospitals NHS Trust
4. Adequate literacy to be able to complete questionnaire and willing to take part in the study and sign a consent form

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
240

Key exclusion criteria
Patients with urgent referral and with history of malignancy, HIV or diagnosis requiring involvement of palliative care team.

Date of first enrolment
01/11/2005

Date of final enrolment
01/01/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nightingale House
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Sponsor information

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Record Provided by the NHSTCT Register - 2006 Update - Department of Health

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Funder(s)

Funder type
Government

Funder Name
Ashford and St Peter's Hospitals NHS Trust (UK) Own Account

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