ISRCTN11899548 https://doi.org/10.1186/ISRCTN11899548

Chronic Pain Self-Management (PSM) for the elderly

Submission date 20/05/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/07/2004	**Overall study status** Completed	
Last Edited 31/07/2008	**Condition category** Signs and Symptoms	

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
5 RO1 NR007787-02

Study information

Scientific Title

Acronym
PSM Study

Study objectives
The primary goal of this study is to evaluate the efficacy of a pain self-management group intervention (SMG), as compared with a control condition (BOOK), in decreasing physical disability, pain, pain-related interference with activities, and depression in older retirement community residents with chronic pain. The hypotheses are as follows:
1. At post-treatment and each follow-up, participants assigned to SMG, as compared with participants assigned to BOOK, will report less physical disability (primary outcome), and lower pain intensity, pain-related interference with activities, and depressive symptom severity (secondary outcomes)
2. Participants assigned to SMG, as compared with participants assigned to BOOK, will show greater pre- to post-treatment increases in self-efficacy and use of adaptive pain coping strategies and greater decreases in catastrophizing. Significant differences between SMG and BOOK groups in pain-related beliefs and coping strategies will be maintained at 6-month and 1-year follow-ups.
3. Pre- to post-treatment changes in specific pain-related beliefs (catastrophizing, self-efficacy) and coping strategies (Chronic Pain Coping Inventory subscales) will be associated significantly with changes in physical and social functioning, pain intensity, and depression over the same period among SMG participants. These changes in beliefs and coping strategies will be maintained at 6-month and 1-year follow-ups.

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)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Chronic pain

Interventions
After all participants from a facility have completed the baseline questionnaires, the facility is randomised to receive either the BOOK or the SMG.

SMG intervention:
This consists of seven weekly 90-minute group sessions. The SMG group facilitator telephones each participant at 12, 16, 22, and 30 weeks after the final group session. During the booster phone calls, facilitators inquire about pain and functioning, current pain management plans, and successes and obstacles in meeting pain management goals, as well as provide encouragement and assistance in problem-solving obstacles encountered in pain management.

BOOK intervention:
Participants receive a copy of The Chronic Pain Workbook, 2nd Edition. Facilitators telephone participants 1 and 4 weeks after participants receive the workbook. BOOK participants receive follow-up phone calls at the same intervals to control for attention.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Roland-Morris Disability Questionnaire (RMDQ)

Secondary outcome measures
1. Brief Pain Inventory (BPI)
2. Geriatric Depression Scale (GDS)

Overall study start date
01/01/2004

Completion date
01/01/2005

Eligibility

Key inclusion criteria
1. Adults 65 years or older
2. Non-cancer musculoskeletal pain greater than three months duration that interferes with daily activities
3. Can read and comprehend questionnaires in English
4. No or minimal cognitive impairment
5. Have not had surgery within the past six months
6. Do not have surgery planned in the next six months

Participant type(s)
Patient

Age group

Senior

Sex
Both

Target number of participants
273

Key exclusion criteria
Current, active cancer

Date of first enrolment
01/01/2004

Date of final enrolment
01/01/2005

Locations

Countries of recruitment
United States of America

Study participating centre
550 16th Ave
Seattle
United States of America
98122

Sponsor information

Organisation
NIH/National Institute of Nursing Research (USA)

Sponsor details
Bldg. 45, Rm 3AN12
45 Center Drive
MSC 6300
Bethesda
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20892-6300

Sponsor type
Government

ROR

https://ror.org/01y3zfr79

Funder(s)

Funder type
Government

Funder Name
National Institutes of Health (NIH) (USA) (ref: 5 RO1 NR007787-02)

Alternative Name(s)
Institutos Nacionales de la Salud, US National Institutes of Health, NIH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

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?
Protocol article	Protocol	30/07/2004		Yes	No
Results article	Descriptive study results	08/11/2005		Yes	No
Results article	RCT results	15/08/2008		Yes	No