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Study of practice pharmacist-led management of long-term pain

Submission date 11/12/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/01/2010	**Overall study status** Completed	
Last Edited 09/05/2013	**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

Protocol serial number
G0701769; pRGF/106/09

Study information

Scientific Title
A pilot randomised controlled trial of general practice-based, pharmacist-led, management of chronic pain

Acronym

PIPPC

Study objectives
We wish to conduct a definitive trial that tests whether pharmacists advice or pharmacists advice and prescribing will lead to better patient functioning and/or better pain control than standard care. This exploratory randomised controlled trial (RCT) will support the development and test the feasibility of conducting a future large multi-centred RCT to evaluate practice-based, pharmacist-led management of chronic pain in primary care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North of Scotland Research Ethics Service, Committee 1 (NoSRES) approved on the 30th November 2009 (ref: 09/S0801/107)

Study design
Exploratory randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

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

Interventions
There are three arms in this study:
1. Pharmacist review: pharmacist medication review with recommendations for changes in pain medication made to GPs for indirect implementation
2. Pharmacist prescribing: pharmacist medication review with pain management recommendations implemented directly by pharmacist at a face-to-face consultation with the patient
3. Standard care provided by GP (control)

Total duration of treatment for pharmacist prescribing arm is 31 minutes. Follow-up may take place between 2 - 4 weeks after initial consultation and take place at maximum twice a month for the 6-month follow-up period of the study. The follow-up period for all arms is 6 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Information from this pilot RCT will be used to inform final selection of a single primary outcome measure from the following:
1. 12-item short form health survey (SF-12)

2. Health Utilities Index mark 2 and mark 3 (HUI 2/3)
Administered for self-report, postal questionnaire at baseline, three and six month follow-up.

Key secondary outcome(s))
1. The Chronic Pain Grade (assessing severity of pain)
2. The Hospital Anxiety and Depression Scale (assessing level of anxiety and depression)
Questionnaires are administered as self-report, postal questionnaire at baseline, three and six month follow-up.

Completion date
01/11/2010

Eligibility

Key inclusion criteria
1. GP practices: any general practice with an existing practice pharmacist service
2. Pharmacists: a registered prescriber with evidence of appropriate professional indemnity cover
3. Patients:
3.1. Male and female patients
3.2. Aged over 18 years old
3.3. Chronic pain (defined as pain lasting more than 13 weeks)
3.4. Receiving regular prescribed medication for pain

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. GP practices: no existing practice pharmacists
2. Pharmacists: not a registered prescriber or does not have evidence of appropriate professional indemnity cover
3. Patients:
3.1. Under 18 years old
3.2. Not experiencing chronic pain
3.3. Concomitant severe mental health problems
3.4. Terminal illness
3.5. Recent bereavement
3.6. Known alcohol or drug addiction

3.7. Unable to give informed consent
3.8. Malignant pain
3.9. Recent participation in research
3.10. Any other reason at the discretion of the GP for whom the intervention is considered inappropriate

Date of first enrolment
04/01/2010

Date of final enrolment
01/11/2010

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Centre of Academic Primary Care
Aberdeen
United Kingdom
AB25 2AY

Sponsor information

Organisation
University of Aberdeen (UK)

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK) (ref: G0701769)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Results article	results	05/04/2013		Yes	No