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Proactive clinical review of patients taking opioid medicines long-term for persistent pain led by clinical pharmacists in primary care teams feasibility study

Submission date
18/02/2020

Recruitment status
No longer recruiting

Registration date
31/07/2020

Overall study status
Completed

Last Edited
28/04/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Persistent pain affects almost half of UK adults. Use of opioids (morphine-like painkillers) for persistent pain has dramatically increased but opioids do not help most patients and often cause side-effects. People taking regular opioids are also more likely to suffer bone fractures, addiction and overdose. Guidelines say patients on long-term opioids should be reviewed regularly, but often this does not happen.
This study is the second stage of a 5-year National Institute for Health Research funded research programme. The programme comprises of three linked workstreams to develop and test a clinical pharmacist-led primary care intervention (PROMPPT), and an associated clinical pharmacist training package which aims to reduce opioid use for people with persistent pain (where appropriate) and support self-management for those with persistent pain in primary care. This is the second work stream which is a non-randomised feasibility study and nested mixed methods process evaluation. This is will inform the refinement of the PROMPPT intervention, clinical pharmacist training package and the main trial design in workstream 3 of the programme.

Who can participate?
Adults over 18 years, prescribed any opioid for chronic non-cancer pain continuously for ≥6 months.

What does the study involve?
Patients with persistent pain who have been prescribed opioids regularly for 6 months will be offered an initial appointment for a face-to-face consultation with the clinical pharmacist in a private consulting room at their GP surgery. Management plans will arise from shared decision making.

Management plans may include opioid tapering but this will not be mandatory, also advice and goals relating to self-management, signposting to information resources, signposting or referral to appropriate community services, for example, physiotherapy, exercise classes, IAPT

(Improving Access to Psychological Therapies) services, and, for more complex cases, discussion /collaboration with the GP and referral to specialist services, including specialist pain services if needed.

Follow-up will be arranged according to clinical need. Patients will also be provided with a clear plan for how to contact the clinical pharmacist between appointments if needed. Follow-up appointments may be conducted face-to-face or by telephone, according to clinical need and patient preference, and are anticipated to be shorter in duration (no longer than 15 minutes).

What are the possible benefits and risks of participating?
There are no direct benefits to taking part the hope being that what is learned with help patients with persistent pain in the future. this study is part of a programme aiming to improve the care offered by GP practices to patients using opiods for persistent pain. There are no risks in terms of physical harm or safety involved in taking part.

Where is the study run from?
Keele University Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
April 2020 to September 2021

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Prof. Christian Mallen
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Study website
https://www.promppt.co.uk/

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
275857

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1.0, IRAS 275857, CPMS 45200

Study information

Scientific Title
Proactive clinical Review of patients taking Opioid Medicines long-term for persistent Pain led by clinical Pharmacists in primary care Teams (PROMPPT). A non-randomised Feasibility Study with mixed methods process evaluation.

Acronym
PROMPPT-FS

Study objectives
This study is part of a 5-year research programme comprising three linked workstreams to develop and test a clinical pharmacist-led primary care intervention (PROMPPT) and an associated clinical pharmacist training package which aim to reduce opioid use for people with persistent pain (where appropriate) and support self-management for those with persistent pain in primary care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/06/2020, North of Scotland Research Ethics Committee ((Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, UK; +44 (0)1224558458; nosres@nhs.net), ref: 20/NS/0067

Study design
Nested mixed methods process evaluation including a cluster-randomized trial and qualitative data collection

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)

GP practice

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
Patients with persistent pain who have been prescribed opioids regularly for 6 months will be offered an initial appointment for a face-to-face consultation with the clinical pharmacist in a private consulting room at their GP surgery. This first consultation, (approximately 30 min) will begin with a holistic assessment of the patient's persistent pain including the impact of pain, followed by a personalised discussion to explore the patient's own experience of the effects (wanted/unwanted, useful/bothersome) of opioids. Motivational interviewing techniques will be used to explore patient's reasons for changing their opioid medicines, their readiness to change and any ambivalence, before agreeing an individualised management plan.

Management plans will arise from shared decision making. The plan may include opioid tapering but this will not be mandatory, for example, if the patient obtains continued useful benefit from moderate dose opioids, without experiencing troublesome side-effects. Where changes to medicines are agreed, SMART (specific, measurable, achievable, realistic, timerelated) goal setting will be used to facilitate the translation of intentions into action. Important barriers to reducing opioids specific to the individual, such as fear of pain worsening and/or withdrawal symptoms following opioid reduction will be addressed.

Management plans may also include advice and goals relating to self-management, signposting to information resources, signposting or referral to appropriate community services, for example, physiotherapy, exercise classes, IAPT (Improving Access to Psychological Therapies) services, and, for more complex cases, discussion/collaboration with the GP and referral to specialist services, including specialist pain services if needed.

Follow-up will be arranged according to clinical need. Patients will also be provided with a clear plan for how to contact the clinical pharmacist between appointments if needed. Follow-up appointments may be conducted face-to-face or by telephone, according to clinical need and patient preference, and are anticipated to be shorter in duration (no longer than 15 minutes).

Intervention Type
Mixed

Primary outcome measure
Feasibility outcome measures:
1. Availability and recruitment of eligible patients, the proportion scheduling and attending clinical pharmacist appointments and retention to 3-month follow-up:
1.1. Proportion of patients eligible (out of all GP registered patients) to be mailed a study invitation
1.2. Proportion of patients returning a baseline questionnaire (out of those mailed a study

invitation)
1.3. Proportion of participants attending the initial PROMPPT consultation with the clinical pharmacist (out of those who returned the baseline questionnaire)
1.4. Proportion of participants who have at least one follow-up appointment scheduled (out of those who attend the initial consultation)
1.5. Proportion of participants who fail to attend one or more scheduled follow-up appointments (out of those who are scheduled a follow-up following the initial consultation)
1.6. Proportion of participants returning a 3-month follow-up questionnaire (out of those consenting to complete questionnaires at baseline)
2. Completeness of data collection: Missing data rates will be calculated for each outcome measure in the baseline and follow-up self-report questionnaires at each data collection time-point (baseline and 3-month)
3. Fidelity of intervention delivery per protocol:
3.1. Proportion of times that use of each intervention component is recorded in intervention case report forms (CRFs)
3.2. Proportion of patients being treated per-protocol (out of all patients who attended the initial clinical pharmacist appointment)
3.3. Findings from qualitative analysis of observed/audio-recorded consultations
4. Suitability of a self-reported pain medicines use questionnaire to calculate mean daily morphine equivalent dose:
4.1. Completeness of response to pain medicines use questionnaire
4.2. Comparison of average daily morphine equivalent dose (MED) calculated using data from self-report questionnaires with MED calculated using prescription data from electronic medical records at baseline and 3-month follow-up
5. Suitability of the health resource use questionnaire for use in a future health economic evaluation: Rate and completeness of response to healthcare resource use and productivity questionnaire
6. Barriers to and facilitators of successful delivery of the intervention:
6.1. Findings from observed/audio-recorded consultations
6.2. Findings from interviews with patients, clinical pharmacists and GPs
7. The acceptability and credibility of the intervention to patients:
7.1. Responses to the Acceptability Questionnaire
7.2. Findings from interviews with patients
8. Acceptability of the intervention and training to clinical pharmacists and GPs, and the feasibility of delivering the intervention in general practice: Findings from interviews with clinical pharmacists and GPs

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/12/2019

Completion date
24/09/2021

Eligibility

Key inclusion criteria
Prescribed any opioid analgesic (defined as any opioid or opioid/paracetamol combination analgesic from sections 4.7.2 and 4.7.1 British National Formulary[ref]) for chronic non-cancer

pain continuously for ≥6 months, (≥ one 28-day opioid prescription issued at least every two months in previous 6 months)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Total final enrolment
148

Key exclusion criteria
1. Acute pain
2. Cancer pain
3. Terminal illness (life expectancy < 6 months)
4. Vulnerable patients (e.g. severe mental illness, learning difficulties, dementia)
5. Current treatment for substance misuse
6. Unable to understand English

Date of first enrolment
26/10/2020

Date of final enrolment
01/03/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Keele University Clinical Trials Unit
David Weatherall Building
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ST5 5BG

Sponsor information

Organisation
Keele University

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Sponsor type
University/education

Website
https://www.keele.ac.uk/research/raise/governanceintegrityandethics/

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 11/09/2023:

The results of this study will inform the refinement of the intervention and associated pharmacist training package ahead of a large multicentre cluster randomised controlled trial to test clinical and cost effectiveness. Our Patient Advisory Group will advise on how to translate these into easily understandable messages and on how best to disseminate the results to the wider public. We will feedback a summary of the results to participating GP practices and publish a summary on the PROMPPT research programme website (http://www.promppt.co.uk) and will use social media to promote the findings via our dedicated Twitter feed. Planned publication in a high-impact peer reviewed journal .

Previous publication and dissemination plan:

All foreground intellectual property (IP) arising from this study will be managed by Keele University. A consortium agreement between North Staffordshire CCG and Keele University assigns all foreground IP to Keele University and provides the legal framework for identification, management, protection and exploitation of IP. The copyright of all materials will belong to Keele University.
On completion of the study the data will be analysed and a final study report prepared. This report will be included in the annual report submitted to NIHR in accordance with the conditions of the grant award. All publications, presentations, correspondence and advertisements arising or related to the grant must acknowledge NIHR as the study's funding source. When acknowledging NIHR UK support, the grant reference number must be quoted.
The results of this study will be made widely and freely available to all stakeholders in ways that are easy to access at no cost. Our Patient Advisory Group will advise on how to translate these into easily understandable messages and on how best to disseminate the results to the wider public. We will feedback a summary of the results to participating GP practices by letter and publish these on the PROMPPT research programme website (http://www.promppt.co.uk) and on the Keele University School of Primary, Community and Social Care website (https://www.keele.ac.uk/pchs/). In addition to publications in open-access peer-reviewed journals, we will use our website, NHS networks and links to professional bodies to support the dissemination of the findings to all stakeholders and will use social media to promote the findings via our dedicated Twitter and Facebook feeds.

Intention to publish date
30/04/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

Added 08/01/2024:
The name and email address of the investigator/body who should be contacted for access to the datasets:

The School of Medicine, Keele University should be contacted for access to datasets: medicine.datasharing@keele.ac.uk
This site can be accessed to obtain the relevant request forms: https://www.keele.ac.uk/health/fmhsresearchthemes/
The type of data that will be shared:
The datasets have to be requested on a case-by-case basis. To access data, reasoning has to be provided in the application form along with a study protocol and a short CV for the study CI/PI. Only team members listed in the application form should have access to the data. Consent from the participants would have been obtained, if necessary for the study and any data provided would be anonymised accordingly. Information on how Keele uses information can be found here:
https://www.keele.ac.uk/legalgovernancecompliance/legalandinformationcompliance/informationgovernance/

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Protocol file	version 1.0	30/04/2020	18/09/2023	No	No
Results article		25/04/2025	28/04/2025	Yes	No