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Medicines optimisation in cancer pain

Submission date 21/01/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/01/2015	**Overall study status** Completed	
Last Edited 12/09/2022	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/trials/a-study-looking-at-improving-cancer-pain-managed-in-the-community-impacct

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17969

Study information

Scientific Title
IMPACCT: exploratory study of a community pharmacy pain medicines consultation for patients with cancer pain

Study objectives
The plan is to interview patients suffering from cancer pain in order to gain insights into their needs in relation to pharmacies and medicines. With this information and a workshop with healthcare practitioners a community pharmacy based service will be designed and implemented to help patients with cancer pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds West REC, 15/10/2014, ref: 14/YH1126

Study design
Non-randomised; Interventional and Observational

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Cancer

Interventions
Current interventions as of 14/12/2016:
Stage 1
Patients with pain from advanced cancer will be interviewed to find out how they use their community pharmacy. They will discuss continuity of use, what experiences they have of community pharmacy services, and what would be helpful to them from a community pharmacy service. The trialists will also explore how services can be provided for patients with pain from cancer.

Stage 2
A multi-stakeholder workshop will be held inviting pharmacists, doctors, nurses, policy makers and educators as well as academics. They will explore what needs and barriers exist for the provision of a community pharmacy based medicine optimisation service for patients suffering from cancer pain. Baseline questionnaires will also be completed with healthcare professionals about community pharmacy services for patients with cancer pain.

Stage 3
The design of the service will be finalised and patients recruited. After baseline questionnaires, a medicine optimisation service will be provided for patients with cancer pain to help them get the most benefit from the medicines they are taking. Post-consultation questionnaires will be completed with the patients, pharmacists and healthcare professionals involved.

Previous interventions:
Medicines Use Review (MUR) type intervention in a community pharmacy specifically for patients with cancer pain.

Intervention Type
Other

Primary outcome measure
Current primary outcome measures as of 14/12/2016:
The acceptability of the pain medicines consultation to patients, assessed by postal questionnaire two weeks after their final consultation

Previous primary outcome measures:
Feasibility of the process; Timepoint(s): by the end of the study

Secondary outcome measures
Added 14/12/2016:
The feasibility of delivering the pain medicines consultation to patients with advanced cancer, assessed by how many patients are recruited and whether the consultations can be delivered to them

Overall study start date
30/12/2014

Completion date
14/04/2017

Eligibility

Key inclusion criteria
Stage 1:
1. Aged 16 or over
2. Have advanced cancer and pain
3. Been receiving strong opiods for 2 weeks or more (morphine, fentanyl, buprenorphine, diamorphine, hydromorphone, methadone or oxycodone)
4. Have a good level of spoken and written English (we do not have the resources to employ an

interpreter at this time)
5. Have the capacity to provide informed consent to participate
6. Be deemed well enough to take part by their healthcare provider

Stage 3 - as well as the criteria for stage 1 the participants should:
1. Regularly use the pharmacies participating in the study it is not feasible to train all the local pharmacists to provide this service at this point but may be an option for future role out.

Patients with advanced cancer will be defined as:
Those with metastatic cancer (histological, cytological or radiological evidence) AND/OR those receiving anti-cancer therapy with palliative intent

Patients with pain will be defined as:
Those receiving strong opiod analgesic treatment for cancer symptom-related pain AND/OR those receiving analgesics for treatment of cancer therapy-related pain

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 45; UK Sample Size: 45

Key exclusion criteria
Stage 1 and 3:
1. Are unconscious or confused
2. Are, in the opinion of the clinician, unable to understand and complete the interview or questionnaires (due to cognitive impairment for example)
3. Are unwilling to provide informed consent
4. We are not looking to recruit patients in the last days of life so we will exclude those who have received anticipatory medicines in readiness for this

Stage 3 only:
1. They do not use one of the participating pharmacies (although these patients may be included at a later date if the study is expanded)
2. Patients who are deemed ethically inappropriate to approach for example where death is imminent.

Date of first enrolment
30/12/2014

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Bradford
Richmond Road
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Sponsor information

Organisation
University of Bradford

Sponsor details
Richmond Road
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Sponsor type
University/education

ROR
https://ror.org/00vs8d940

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
The study has been submitted to a journal and it is envisaged that it will be accepted by the end of 2018.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
Data will be held at Bradford University on password-controlled computers and then archived at Leeds University. Patient level data will not be available unless there is no risk of identifying patients involved.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	medicines optimisation results	01/06/2019	24/06/2019	Yes	No
Results article	patient interview results	01/07/2018	24/06/2019	Yes	No
Plain English results		08/09/2022	12/09/2022	No	Yes