

Medicines optimisation in cancer pain

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

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

Contact name

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Non-randomised; Interventional and Observational

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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 opioids 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 opioid analgesic treatment for cancer symptom-related pain AND/OR those receiving analgesics for treatment of cancer therapy-related pain

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

University of Bradford

Richmond Road

Bradford

United Kingdom

BD7 1DP

Sponsor information

Organisation

University of Bradford

ROR

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

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