# Medicines optimisation in cancer pain

<b>Submission date</b> 21/01/2015	<b>Recruitment status</b> No longer recruiting	<ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>		
<b>Registration date</b> 21/01/2015	<b>Overall study status</b> Completed	<ul> <li>[] Statistical analysis plan</li> <li>[X] Results</li> </ul>		
Last Edited 12/09/2022	<b>Condition category</b> 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

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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

DOLII

#### 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 Bradford United Kingdom BD7 1DP

### Sponsor information

**Organisation** University of Bradford

**Sponsor details** Richmond Road Bradford England United Kingdom BD7 1DP

**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
<u>Results article</u>	patient interview results	01/07/2018	24/06/2019	Yes	No
<u>Plain English results</u>		08/09/2022	12/09/2022	No	Yes