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Improving the management of pain from advanced cancer in the community

Submission date 30/09/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2015	**Overall study status** Completed	
Last Edited 12/09/2022	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-comparing-2-different-ways-of-pain-management-support-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
19024

Study information

Scientific Title
Improving the management of pain from advanced cancer in the community: a feasibility randomised controlled trial

Acronym
IMPACCT

Study objectives
Within oncology services, early screening and referral of community based patients with pain from advanced cancer, combined with routine pain assessment and monitoring, will reduce the extent of pain and psychological distress reported by the patient.

Ethics approval required
Old ethics approval format

Ethics approval(s)
15/YH/0235

Study design
Randomised; Interventional; Design type: Process of Care, Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Topic: Cancer; Subtopic: Colorectal Cancer, Upper Gastro-Intestinal Cancer, Breast Cancer, Lung Cancer, Prostate Cancer; Disease: Breast, Colon, Lung (non-small cell), Prostate

Interventions
160 participants will be recruited, and randomly allocated on an equal basis to receive either the intervention or usual care or standard care. Participants allocated to the intervention will be referred to their local palliative care team and further intervention will take place within the palliative care setting. The participants will be asked to complete a questionnaire pack at baseline when they enter the study, at 6 weeks and then at 12 weeks after this date. This will be completed in clinic at the baseline visit and sent to their home address at the 6 and 12 week

visits. A Researcher (who will be blind to treatment allocation) from the University of Leeds will call the participant and offer to go through the answers to the questionnaires if they prefer.

Intervention Type
Other

Primary outcome measure
1. Uptake and retention rate of each intervention recorded throughout the study period
2. Pain severity, measured using the Brief Pain Inventory at 6 and 12 weeks

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/10/2015

Completion date
04/04/2018

Eligibility

Key inclusion criteria
1. Aged 16 years or over
2. Diagnosis of advanced incurable disease (locally advanced or metastatic) in one of the following disease areas:
2.1. Breast
2.2. Colon or rectal
2.3. Non-small cell lung cancer
2.4. Prostate
2.5. Upper GI
3. Experiencing cancer related pain (tumour or treatment related) (as assessed by the Clinician) with an average pain score of = 4 on the “average pain” item of the Brief Pain Inventory
4. Has the potential to benefit from palliative care support as assessed by the Clinician
5. An expected prognosis of 12 weeks or more
6. The patient is living at home
7. The patient lives in the local catchment area for a participating hospice
8. The patient is able and willing to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 161; UK Sample Size: 161

Total final enrolment
161

Key exclusion criteria
1. Previously referred to palliative care team
2. The patient has insufficient literacy, or proficiency in English to contribute to the data collection required for the research
3. Patients will be excluded if they lack capacity to provide informed consent to this trial
4. Patients with dominant chronic pain that is not cancer related (tumour or treatment)

Date of first enrolment
01/10/2015

Date of final enrolment
26/01/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cancer Research UK
Beckett Street
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
University of Leeds

Sponsor details
School of Healthcare
Baines Wing
Woodhouse Lane
Leeds
England
United Kingdom
LS2 9JT

Sponsor type

Hospital/treatment centre

ROR
https://ror.org/024mrxd33

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
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/03/2018		Yes	No
Results article		01/12/2021	13/07/2022	Yes	No
HRA research summary			28/06/2023	No	No