ISRCTN86926298 https://doi.org/10.1186/ISRCTN86926298

CAPTURE: Improving pain assessment for cancer patients, a cluster randomised control pilot trial

Submission date 31/08/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 01/09/2023	**Overall study status** Completed	
Last Edited 16/12/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
When people have cancer, more than 70% of them experience long-lasting pain. Not treating this pain properly makes their quality of life worse, affects their emotions, makes things harder, and increases how much they need to use healthcare services, which also costs more money. Right now, there's no consistent way of dealing with this pain, like a set of steps everyone follows, proper training, or a clear system for reporting it. Because of this, we can't manage cancer pain as well as we should. We don't know much about what makes doctors assess and treat pain in cancer patients when they come for regular check-ups. This shows that we really need a clear and shared way of dealing with cancer pain.

Our aim is to check if we can put a clear plan for managing pain into the regular check-ups for cancer patients and also to do a special test where we try this plan in three different cancer centers in the northern part of England.

Who can participate?
Patients aged 18 years or older who are attending a participating outpatient service during the trial period

What does the study involve?
We're involving 12 places where cancer patients go for check-ups, spread across three big centers in West Yorkshire. We'll randomly choose which places will try a new approach called EPAT, and which will stick with the regular way of doing things. We'll ask people with cancer who go to these places to help by sharing their experiences and medical information with us. The study participation will take 2 months.

What are the possible benefits and risks of participating?
Patients in the intervention arm may benefit from earlier access to analgesia, receiving advice for pain and medicines and timely access to palliative care. If indicated, we will submit an external funding bid in 2023 for a definitive phase-III randomised controlled trial (RCT).
No risks.

Where is the study run from?
University of Leeds (UK)

When is the study starting and how long is it expected to run for?
August 2022 to September 2025

Who is funding the study?
Yorkshire Cancer Research (UK)

Who is the main contact?
Dr Matt Mulvey, m.r.mulvey@leeds.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Matt Mulvey

ORCID ID
https://orcid.org/0000-0002-6357-3848

Contact details
Academic Unit of Primary and Palliative Care
Leeds Institute of Health Sciences
University of Leeds
Worsley Building, 10..39b
Clarendon Way
Leeds
United Kingdom
LS2 9NL
+44 1133 430836
m.r.mulvey@leeds.ac.uk

Type(s)
Public

Contact name
Dr Olivia Robinson

Contact details
Academic Unit of Primary and Palliative Care
Leeds Institute of Health Sciences
Worsley Building
Room 10.39
Clarendon Way
Leeds
United Kingdom
LS2 9NL

+44 7984310078
o.c.robinson@leeds.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
320470

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 55348, L428

Study information

Scientific Title
Cancer Pain-assessment toolkit for use in routine oncology outpatient services: Multi-centre cluster randomised pilot trial

Acronym
CAPTURE

Study objectives
There will be a significant reduction in pain severity and cost effectiveness in cancer patients exposed to routine pain assessment compared to those receiving usual care.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/04/2023, Yorkshire and the Humber – South Yorkshire Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 207 104 8165; southyorks.rec@hra.nhs.uk), ref: 23/YH/0040

Study design
Interventional cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic pain in cancer patients

Interventions

Study design

We will use a multi-centre cluster randomised pilot trial, with a nested qualitative sub-study. We will recruit twelve outpatient services across three tertiary oncology referral centres in West Yorkshire (six clinics will receive the intervention and six clinics will receive the control). Randomisation (1:1) will occur at service-level to deliver the intervention (EPAT plus usual care) or control (usual care). Patients with cancer will be recruited from within participating oncology outpatient services to provide patient reported outcome data and medical notes review data. The study will be jointly co-ordinated by the Leeds Institute for Health Sciences and the Leeds Clinical Trials Research Unit (CTRU).

Usual care

EPAT will not be available for usual care clusters. The clusters allocated to the control group will continue to provide usual care only. It is anticipated that usual care will consist of a non-standardised pain assessment by nursing and/or medical staff, followed by a management decision. At present in the UK, this part of cancer care is not carried out in a structured, systematic way. While pharmacological management in the usual care clusters will be based on the principles of WHO guidelines, the way in which these guidelines are used is not standardised or systematic in cancer centres in the UK. The pain assessment and management given at each cluster will be reported as part of the study outcomes by collecting data from patients medical notes on whether a pain assessment was undertaken, analgesic prescriptions and healthcare resource use.

EPAT plus usual care (intervention)

Intervention clusters will receive EPAT plus usual care. At each intervention cluster implementation of EPAT will commence following HCP training and will run for a maximum of 12-weeks.

The EPAT intervention will include:

A training module to support clinician education, consisting of a short presentation about EPAT and detailed instructions of how to use EPAT forms during the patient consultation. This will be followed by role-play situation demonstrating how to use EPAT in practice.

A pain screening module conducted by clinic healthcare assistant, nurse or clinician to identify cancer patients who have, or have had, moderate to severe pain within the past 3 days: i.e. pain rated as being ≥3/10 on a 0-10 numerical pain rating scale.

A detailed pain assessment module conducted by a physician or clinical nurse specialist for patients with a pain screen ≥3/10 on a 0-10 NRS of worst pain in past 72 hours. The detailed pain assessment will evaluate the location and severity of the patients' pain, as well as the underlying pain etiology and mechanisms, and any factors that exacerbate or relieve the patients' pain.

A basic pain management algorithm/protocol (based on WHO analgesic prescribing ladder) to guide analgesic prescribing and/or onward referral to a pain specialist. This management algorithm is linked to the previous detailed pain assessment module by listing (i) tailored analgesic prescribing, (ii) provision of self-management support education, (iii) onward referral to a pain specialist teams.

EPAT will be in paper form and implemented within existing policy in intervention clusters. Clinicians at these sites will receive face-to-face training on using EPAT. All patients with cancer

attending intervention clusters, will receive the pain screening module of the EPAT intervention. Patients with a pain score of ≥3/10 will also receive the detailed pain assessment module of the EPAT intervention.

The EPAT form will be attached to the front of patients' notes by a clinic healthcare assistant or a clinic nurse and given to the consulting physician.

Intervention champion
At least one HCP from each intervention cluster will take on the role of 'EPAT champion' to lead local implementation of the intervention, with support from the project team. Intervention champions will be required to:
Have oversight of the outpatient service (cluster) randomised to the intervention arm;
Have direct interaction with patients and their medical notes;
Have direct contact with clinical staff responsible for pain management and;
Experience of rolling out new staff processes would be desirable but this is not essential.
Identification of EPAT champions will be conducted in partnership with the managers (or clinical leads) at each intervention cluster. We anticipate that champions will attend a one-off training session, led by the CI (Dr Mulvey) and/or Research Fellow (Dr Robinson).

Intervention cluster staff training
Intervention clusters will receive EPAT plus usual care. Oncologists and oncology nurses working in the cluster will be trained to deliver the intervention by the EPAT champion, with support from the CI, RF or delegate. Training of all staff within the cluster and EPAT implementation will take place over a three-week period (prior to starting participant recruitment) to allow time for the intervention to become established as routine practice.
At each intervention cluster implementation of EPAT will commence following HCP training and will run for a maximum of 12-weeks.

Screening and recruitment of patients to provide PROMS data and medical notes data
Potentially eligible patients will be identified by a research nurse (RN) embedded within oncology outpatient services. The RN will screen the clinic lists for patients who meet the first three of four inclusion criteria and none of the exclusion criteria (see protocol section 5). The list of potentially eligible patients will be discussed with the direct care team.
Potentially eligible patients will be approached at their next clinic visit by a member of their direct care team who will introduce the patient to the RN (or delegate) who will discuss the project in more detail.
If the patient is interested in participating in the study, the RN/delegate will then establish the final inclusion criteria by asking the patient to rate the worst pain they have had in the past 72 hours using a 0-10 Numerical Rating Scale (NRS). If the patient scores 3 or higher on the NRS they will be considered eligible.
The RN/delegate will provide eligible patients with information about the study and answer any questions they may have about participating. Informed consent will then be obtained. Once consented the RN/delegate will give the patient a paper copy of baseline patient-reported outcomes (PROMS) questionnaire to complete before going into their appointment consultation. Patient eligibility and baseline PROMS questionnaire must be established prior to the patient's appointment consultation so that these measures can be captured before they are exposed to the EPAT intervention.
All patients recruited from control and intervention clusters will complete all patient-reported outcome measures at the following time points: baseline (i.e. same day as providing consent to participate), 1 week, 1 month and 2 months following baseline. Consented participants will also be invited to take part in an interview at the end of the study.

Patient-reported outcomes (baseline and follow-up)
Once baseline data is collected and the participant has been registered to the trial, follow-up assessments will be conducted at week-1, month-1, and month-2 to collect patient-reported outcomes. In addition to this, medical record data will be collected from secondary care records by a Research nurse or delegate (i.e. analgesic prescriptions, healthcare resource use, referral to specialist teams) and patient-reported outcomes related to healthcare resource use will be collected at baseline, 1-month and 2-months.

Follow-up data will be collected via an online platform known as REDcap supplemented by reminders including telephone, and text prompts. This will be managed by CTRU. At each post questionnaire follow-up reminders will be sent at day 4, second on day 8 and third on day 11. If a participant has difficulty completing the questionnaires online, assisted completion will be offered whereby they can answer the questions over the phone with a University of Leeds researcher, who will complete a paper hard copy and send to CTRU.

The following patient-reported outcome measures will be used:
-Brief Pain Inventory (BPI)
-EQ-5D-5L measure of general health related quality of life
-Generalised Anxiety Disorder 7-item Scale (GAD-7)
-Patient Health Questionnaire (PHQ-8) measure of depression
-Edmonton Symptom Assessment System (EASA)

Qualitative sub-study
At the end of the trial participants, healthcare professionals and intervention champions from each clinic will be invited to take part in an end-of-study interview. The qualitative sub-study will assess the fidelity and quality of intervention implementation and identify the contextual factors that are associated with any variation in intervention uptake, outcome measures and trial processes. This will enable us to adapt and refine how EPAT operates to produce improved pain management outcomes for patients with pain from cancer.

A random selection of up to 20 participants will be identified by study arm and will be invited to take part in a telephone, video interview or in-person interview with a researcher at the end of the study. This will include recruitment of HCPs, and patients from the intervention and control sites. The interviews will be guided by a set of prompts (topic guide) exploring issues related to the uptake, use and acceptability of EPAT (including barriers and facilitators to use), as well as adherence and changes in clinicians' pain assessment practice or patients' pain control (e.g. tailored analgesic prescribing) and fidelity of delivery and contamination.

All champions involved in delivery or management of the intervention will also be invited to take part in a telephone, video-call or in-person interview with a researcher at the end of the study.We will aim to interview a minimum of 4 intervention champions.Interviews will ask questions that provide insight into their acceptability of trial procedures, training materials, of the intervention itself and their experiences regarding any interactions they have had with trial participants.

Intervention Type
Mixed

Primary outcome(s)
1. Pain measured using the Brief Pain Inventory (BPI) at screening, baseline, 1 week, 1 month, 2 months
2. EQ-5D-5L measure of general health related quality of life at baseline, 1 week, 1 month, 2

months
3. Anxiety: Generalised Anxiety Disorder 7-item Scale (GAD-7) at baseline, 1 month, 2 months
4. Depression: Patient Health Questionnaire (PHQ-8) measure of depression at baseline, 1 month, 2 months
5. Symptoms: Edmonton Symptom Assessment System (EASA) at baseline, 1 month, 2 months

Key secondary outcome(s))
1. Basic demographics: age, ethnicity, marital status, sex, highest achieved education level by patient report at baseline
2. Recent medical history, cancer type and stage by patient report at baseline
3. Medications and referral check plus healthcare resource use, analgesic prescriptions, specialist service referral, healthcare resource use measured using patient records at baseline, 1 month, 2 months
4. Site level usual care offered and accessed by participant interview at 2 months

Completion date
06/09/2025

Eligibility

Key inclusion criteria
Patients:
1. Attending a participating outpatient service during the trial period and,
2. Aged 18 years or over;
3. Have a diagnosis of cancer;
4. Self-report a score of > = 3 on the 0-10 Numerical Rating Scale (NRS) for worst pain in the past 72 hours;

Healthcare professionals:
1. Work at a participating outpatient service during the study period.

Participant type(s)
Health professional, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment

134

Key exclusion criteria
Patients:
1. Clinical judgement will be used to determine patients that are too ill to take part, including those with severe mental health problems;
2. Considered by their clinical teams to be actively dying;
3. Unable to complete a NRS in English;
4. Are not expected to be available for first follow-up data collection (1-week).

Healthcare professionals:
1. Do not have any contact with oncology outpatient patients.

Date of first enrolment
30/10/2023

Date of final enrolment
11/07/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St James's University Hospital NHS Trust
St James's University Hospital
Gledow Wing
Beckett Street
Leeds
England
LS9 7TF

Study participating centre
Hull Royal Infirmary
Anlaby Road
Hull
England
HU3 2JZ

Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Charity

Funder Name
Yorkshire Cancer Research

Alternative Name(s)
YCR

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from:
- Dr Matt Mulvey, m.r.mulvey@leeds.ac.uk
- Anonymised quantitative patient reported outcome data and anonymised summaries of qualitative data, data available from October 2025 for 5-years
- access to data will be considered on a case-by-case basis for sharing with academic researchers for secondary analysis via secure file transfer system
- consent for sharing data will be obtained from participants
- all data will be anonymised
- no ethical or legal restrictions

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol article		30/10/2025	31/10/2025	Yes	No
HRA research summary			20/09/2023	No	No
Other publications	Process evaluation protocol	27/06/2025	30/06/2025	Yes	No