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The wellbeing-informed shared decisions about oncology management study

Submission date
12/08/2025

Recruitment status
Recruiting

Registration date
13/08/2025

Overall study status
Ongoing

Last Edited
13/08/2025

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Older people with advanced cancer often face difficult decisions about treatment. Many are also living with frailty. In healthcare, frailty is a condition which means that recovery from illness or treatment can take longer or be more difficult. People living with frailty are more likely to experience side effects and complications during cancer treatment. However, frailty is not always assessed or discussed in cancer clinics.
This study aims to test a new approach called the WISDOM intervention to help patients and doctors make more informed, personalised treatment decisions by considering the patient's frailty and overall well-being. The study findings will be used to improve the intervention and plan a bigger future study to test whether it works.

Who can participate?
Patients aged 65 years or older with advanced gastrointestinal (GI) or lung cancer who are being referred to oncology (cancer) clinics in Leeds for possible drug treatment to control their cancer may be invited to take part. Patients must be able to give consent and complete short questionnaires, with support if needed.

What does the study involve?
Patients taking part in the study will:
1. Receive a short wellbeing/frailty assessment before their first oncology appointment.
2. Be given clear, easy-to-understand information to help them prepare for discussing their treatment options in their appointment.
3. Have a consultation with a doctor trained in the WISDOM approach, which involves considering patient wellbeing when discussing treatment options.
4. Complete short questionnaires about their quality of life and experience at two follow-up points (around 2 and 8 weeks after their first oncology appointment).
5. Some patients will also be invited to take part in an interview to share their experiences of the WISDOM approach and taking part in the study.

What are the possible benefits and risks of participating?
The WISDOM approach may help patients feel more involved in decisions and ensure their care better reflects their needs and preferences. There are no direct risks, but some patients may

find it upsetting to talk about their health and treatment options. Patients will be signposted to support if needed.

Where is the study run from?
The study is based at Leeds Cancer Centre and is being led by researchers at the University of Leeds (UK)

When is the study starting and how long is it expected to run for?
October 2022 to July 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Jessica Pearce, j.pearce@leeds.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
321284

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

CPMS 55944

Study information

Scientific Title
Wellbeing-Informed Shared Decisions about Oncology management (WISDOM): a non-randomised feasibility study testing the WISDOM intervention in patients with advanced gastro-intestinal and lung cancer

Acronym
WISDOM

Study objectives
Undertake feasibility testing of the WISDOM intervention to:
1. Explore intervention acceptability and feasibility
2. Identify areas for intervention refinement
3. Clarify areas of methodological uncertainty to inform a future pilot and definitive trial (e.g. recruitment and data collection procedures)

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/07/2025, Yorkshire & Humber - Leeds West Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; -; leedswest.rec@hra.nhs.uk), ref: 23/YH/0082

Study design
Single-centre single-arm non-randomized interventional feasibility study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Frailty-informed care in older adults with advanced gastro-intestinal or lung cancer

Interventions
This feasibility study will begin to evaluate the first protoype of WISDOM*. WISDOM is a complex intervention which has been co-designed with patients, healthcare professionals and academic experts to support the use of frailty assessment to within shared decision-making around systemic therapy for patients with advanced cancer.

*formerly FRAME (frailty-informed cancer management; re-named in response to stakeholder input)

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4. Complete short questionnaires about their quality of life and experience at two follow-up points (around 2 and 8 weeks after their first oncology appointment).
5. Some patients will also be invited to take part in an interview to share their experiences of the WISDOM approach and taking part in the study.

Intervention Type
Other

Primary outcome(s)
In line with feasibility aims, the primary outcomes include the following process measures:
1. Participant uptake/recruitment recorded as the proportion of eligible patients approached and subsequently consented within the study period (6-12 months)
2. Retention at follow-up recorded as the proportion of participants consented who complete PFU1/2 (at 2 and 8 weeks post baseline, respectively)
3. Completeness of data captured in questionnaires at each timepoint (baseline, 2 and 8 weeks), recorded as the proportion of participants completing each questionnaire and the proportion of missing responses for item

Key secondary outcome(s))
Short-term change in quality of life will be evaluated at 2 and 8 weeks post-baseline using the following Patient Reported Outcome Measures (PROMs):
1. EuroQol-5 Dimension (EQ5D)-5L
2. EORTC quality-of-life questionnaires (QLQ)-C30
3. EORTC QLQ-ELD14

The SHARED questionnaire will also be completed by patients at 2 weeks post baseline to evaluate the decision-making process.

Completion date
01/07/2026

Eligibility

Key inclusion criteria
1. Older patients (≥65 years) with colorectal, anal, gastro-oesophageal, pancreatic or lung malignancies (any histology) being referred to oncology primarily for consideration for first-line palliative SACT. This would include medically or technically inoperable stage 3/4 disease.
2. Booked for an oncology new patient appointment with an oncologist who is participating in the study

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group

Senior

Lower age limit
65 years

Upper age limit
1000 years

Sex
All

Key exclusion criteria
1. Patients lacking the capacity to consent to participation
2. Unable to complete patient-reported outcome measures (PROMs) with support

Date of first enrolment
01/08/2025

Date of final enrolment
01/07/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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
The datasets generated during this study are not expected to be made available due to the small sample size, in the interests of maintaining participant confidentiality.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes