

The wellbeing-informed shared decisions about oncology management study

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| Submission date 12/08/2025 | Recruitment status Recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 13/08/2025 | Overall study status Ongoing | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 13/08/2025 | Condition category Cancer | <input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

Contact name

Dr Jessica Pearce

ORCID ID

<https://orcid.org/0000-0002-6553-2652>

Contact details

Patient Centred Outcomes Research Group (PCOR)

Level 5, Clinical Sciences Building

St James' Institute of Oncology

Beckett Street

Leeds

United Kingdom

LS9 7TF

+44 (0)113 343 0998

J.Pearce@leeds.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

321284

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 prototype 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).
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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/024mrx33>

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? |
|-------------------------------|---------------|--------------|------------|----------------|-----------------|
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |