

# The wellbeing-informed shared decisions about oncology management study

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<b>Registration date</b> 13/08/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 13/08/2025	<b>Condition category</b> 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](mailto:j.pearce@leeds.ac.uk)

### **Study website**

<https://pcor.org.uk/the-frailty-informed-cancer-management-frame-study/>

## **Contact information**

### **Type(s)**

Public, Scientific, Principal Investigator

### **Contact name**

Dr Jessica Pearce

### **ORCID ID**

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### **Contact details**

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## **Additional identifiers**

### **EudraCT/CTIS number**

Nil known

### **IRAS number**

321284

### **ClinicalTrials.gov number**

Nil known

## Secondary identifying numbers

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 gastrointestinal 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

## 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 Participant Information Sheet

## 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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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.

## **Intervention Type**

Other

## **Primary outcome measure**

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

## **Secondary outcome measures**

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.

## **Overall study start date**

01/10/2022

## **Completion date**

01/07/2026

## **Eligibility**

**Key inclusion criteria**

1. Older patients ( $\geq 65$  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

**Age group**

Senior

**Lower age limit**

65 Years

**Upper age limit**

1000 Years

**Sex**

Both

**Target number of participants**

30

**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**

England

United Kingdom

**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

### Sponsor details

Woodhouse Lane  
Leeds  
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United Kingdom  
LS2 9JT  
+44 (0)113 243 1751  
governance-ethics@leeds.ac.uk

### Sponsor type

University/education

### Website

<https://www.leeds.ac.uk/>

### 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**

**Publication and dissemination plan**

Planned publication in a peer-reviewed journal

**Intention to publish date****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