ISRCTN87386790 https://doi.org/10.1186/ISRCTN87386790

# The Autonomy study: the ability to make decisions and have a say in the direction of our lives

**Submission date**
14/05/2024

**Recruitment status**
Recruiting

**Registration date**
23/05/2025

**Overall study status**
Ongoing

**Last Edited**
14/05/2025

**Condition category**
Cancer

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

## Plain English summary of protocol

Background and study aims
Older age is linked to the risk of getting cancer. Older patients are also closer to the end of their natural life span. For less fit patients, some cancer treatments can have lots of side effects. This may limit their ability to live normal lives. Some treatments may prolong life, but not always by much in patients with short life spans. This may be due to age and ill health, rather than the cancer. This can make decisions about treatments hard. There may be other treatment options, which have fewer side effects. These treatments may be less good at curing cancer but better at helping people to live a normal, happy life. This is because they have side effects which are easier to put up with. It is important to balance the benefits of treatments with the impact this may have on how a person lives their life. When patients and doctors make these choices, it is called shared decision-making. This is the best way to make treatment choices because the doctor considers the patient's wishes. Some patients would prefer to have treatment that allows them to feel well and live at home caring for themselves for as long as they can and accept that they may live a slightly shorter life. Not all doctors ask their patients about this issue when choosing treatments. Knowing what patients prefer helps doctors to offer the best treatment for that patient. This study will create a new tool to help patients and doctors jointly make the right treatment choices. It will help doctors to understand what a patient prefers in terms of their choice to have a longer life or a better quality of life. There are already tools like this to use in patients whose cancer is not curable, but none for patients where cancer is potentially curable but other factors limit life expectancy.

Who can participate?
Senior cancer patients aged 70 years and over with a pre-existing limited life expectancy based either on their extreme age (≥85 years), frailty or multi-morbidities

What does the study involve?
The study will create a new decision tool which can help patients and doctors to jointly make treatment decisions. The tool will also help doctors to understand what a patient prefers in

terms of their choice to have a longer life or a better quality of life. To do this, the study will invite people who have had a recent or previous diagnosis of potentially curable invasive cancer to take part in a research interview and/or complete a questionnaire.

What are the possible benefits and risks of participating?
The information collected as a result of participating in the study will not have any direct benefit on the care that the participant currently receives, although it could help to improve clinical practice and cancer treatment decision-making for older patients in the future.

There are no specific risks associated with taking part in the study, however, participants may be inconvenienced in terms of the time taken to participate in an interview or complete a questionnaire.

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

When is the study starting and how long is it expected to run for?
March 2023 to March 2027

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

Who is the main contact?
Miss Jenna Morgan, autonomystudy@sheffield.ac.uk (UK)

# Contact information

### Type(s)
Public, Scientific, Principal investigator

### Contact name
Dr Jenna Morgan

### ORCID ID
https://orcid.org/0000-0002-5337-5581

### Contact details
Division of Clinical Medicine
School of Medicine and Population Health
The University of Sheffield
Medical School
Beech Hill Road
Sheffield
United Kingdom
S10 2RX
-
autonomystudy@sheffield.ac.uk

# Additional identifiers

### Integrated Research Application System (IRAS)
334181

### Central Portfolio Management System (CPMS)
66943

### National Institute for Health and Care Research (NIHR)
302481

# Study information

### Scientific Title
The AUTONOMY study: Our ability to make decisions and have a say in the direction of our lives

### Acronym
AUTONOMY

### Study objectives
Can the decision preferences of frail, older patients be elicited using a bespoke tool to explore quality of life versus length of life preferences when making shared decisions about early-stage cancer treatments?

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Approved 17/03/2025, London - Harrow Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8154, 207 104 8357, 207 104 8137; harrow.rec@hra.nhs.uk), ref: 25/PR/0155

### Primary study design
Observational

### Study design
Sequential mixed-methods multi-centre study

### Study type(s)
Quality of life, Treatment

### Health condition(s) or problem(s) studied
Older cancer patients with a naturally limited life expectancy

### Interventions
The study aims to develop a new tool that allows older cancer patients with a naturally limited life expectancy to determine the extent to which they prioritise quality of life or length of life in the context of deciding treatment for early-stage cancer. The study will use sequential mixed methods (qualitative and quantitative) to answer the research question and achieve the aims and objectives. This methodology was chosen for the following reasons:

Qualitative (QUAL) research is exploratory by nature and offers several advantages for studying and understanding decision-making preferences. By engaging with patients and carers directly through semi-structured interviews and focus groups, the study will gain a subjective understanding of the quality of life versus length of life preferences in older patients. The strengths of QUAL methods, such as researcher flexibility and the collection of rich in-depth data, will allow for a more nuanced interpretation of the research topic.

Quantitative (QUANT) research is a valuable approach for hypothesis testing and determining statistical significance. By administering surveys and structured questionnaires to patients and carers, the study will gather a large amount of data that allows for statistical analysis, generalizability and insight into key variables of interest. The strengths of QUANT methods, such as generalizability and statistical analysis, will complement the QUAL strand of the study, and enhance the validity and reliability of the findings.

The project management group will comprise researchers, collaborators and PPI members who will meet every 6 months to monitor progress, address any problems, discuss findings and formulate short- and medium-term plans. This includes establishing an Expert Reference Group (ERG) and a User Advisory Group (UAG). The ERG will include members that possess expertise in the surgical, oncological (oncologists and MacMillan Nurses), gerontological (geriatricians), primary care and psycho-oncological (health psychologists, Nurse Specialists) perspectives of cancer management. The UAG will include PPI collaborators who have already contributed to the design of this study, and additional members will be sought from these and other networks, including the Deep End Research Cluster PPI groups and ‘People in Research'.

Brief Project Overview:
Work Package 1 (WP1): Systematic evidence review and expert reference group. A systematic review looking at the current evidence for decision preferences with regards to quality of life versus length of life in older, frailer adults, and the tools assessing quality of life versus length of life in other settings. The review will inform the expert reference group and interview schedule.

Work Package 2 (WP2): Exploring the role of Quality of life versus Length of life in the frail older patient. This mixed methods sequential package will involve qualitative interviews with frail, older patients estimated to have a limited life expectancy (less than 3-5 years) by their clinical team based on their age/co-morbidities/frailty and cancer diagnosis, to explore their priorities for treatment in terms length of life versus quality of life. Interview responses will be used to design the final survey tool to explore these issues across a wider population to ensure generalizability. The validated QQQ, which we have previously modified for the early cancer setting, will form part of this survey tool.

Work Package 3 (WP3): Develop a new tool to aid decision-making in the frail older cancer population. The study team will develop a new decision support tool for use within the clinical setting to support frail older patients facing cancer treatment decisions, allowing them to explore their priorities in terms of quality of life versus length of life, especially related to independence. This will follow the IPDAS methodology for developing patient decision aids and will include focus group methodology to ensure the tool has content and face validity, test-retest reliability and is usable and acceptable. These findings will then be validated using a small group of patients and clinicians.

The broad timetable for carrying out each stage of the research is as follows:
Year 1: Carry out and publish systematic review; recruit PPI members to the User Advisory Group; apply for ethics approval; and write up scientific review for Expert Reference Group.

Year 2: Develop interview schedule with PPI members and perform/analyse patient interviews; design survey tool using findings from interviews; and disseminate survey.

Year 3: Analysis of survey results; perform and analyse focus groups; design prototype of decision tool; and evaluate tool with patients (user testing).

Year 4: Design final tool; write-up and publish study results.

### Intervention Type
Other

### Primary outcome(s)
1. The role of quality of life versus length of life in the frail older patient measured using data collected during in-depth qualitative interviews and questionnaires with patients and carers during Work Package 2 (WP2)
2. Development of a new decision-support intervention tool to support frail older patients facing cancer treatment decisions using Focus Groups during Work Package 3 (WP3)

### Key secondary outcome(s)
1. Identify the priorities and information needs of frail, older patients regarding cancer treatment (in particular, cancer surgery, chemotherapy and radiotherapy) and their views on the relative importance of maintaining their quality of life and independence, balanced against their wish to undergo potentially burdensome therapies that may extend their life but reduce its quality, using qualitative interviews.
2. Design and disseminate a survey tool to apply to a wider group of cancer patients to establish the generalisability of the results found in the qualitative interviews.
3. Design a decision tool to capture patients' preferences for quality of life versus length of life using data from the interview and questionnaire phase of the study. User and field testing of the tool on a sample of older patients undergoing treatment for cancer, using focus groups.

### Completion date
01/03/2027

## Eligibility

### Key inclusion criteria
1. Older patients (≥70 years old) with a pre-existing limited life expectancy based either on their extreme age (≥85 years), frailty or multi-morbidities
2. Able to give informed consent or if lack capacity have an available relative with a legal power of attorney for health and welfare who will be asked to take part on their behalf
3. Recent or previous diagnosis of potentially curable invasive cancer (breast, lung, prostate, and colorectal) and being offered a choice of standard therapy (usually surgery) versus fitness-adapted therapy (systemic hormonal therapy, radiotherapy, stent, "watch and wait")
4. Caregiver or family member with lasting power of attorney (LPA) for a patient meeting inclusion criteria points 1 and 3
5. There are no language or ethnicity limits as interpreters will be used as required

### Participant type(s)
Patient, Carer

### Healthy volunteers allowed

No

### Age group
Senior

### Lower age limit
70 Years

### Upper age limit
120 Years

### Sex
All

### Key exclusion criteria
1. Patients with advanced cancer where a cure is not possible (ie. metastatic cancer)
2. Patients where surgery is required to prevent emergency short-term crises (such as bowel obstruction)
3. Patients who cannot give consent

### Date of first enrolment
09/05/2025

### Date of final enrolment
01/03/2027

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust**
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
United Kingdom
DN2 5LT

### Study participating centre
**Royal Hallamshire Hospital**
Glossop Road
Sheffield
United Kingdom
S10 2JF

# Sponsor information

### Organisation
Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust

### ROR
https://ror.org/01yc93g67

# 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 data-sharing plans for the current study are unknown and will be made available at a later date

### IPD sharing plan summary
Data sharing statement to be made available at a later date

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | version 1.1 | 11/03/2025 | 07/05/2025 | No | Yes |

| | | | | | |
|---|---|---|---|---|---|
| Participant information sheet | version 1.1 | 11/03/2025 | 07/05/2025 | No | Yes |
| Participant information sheet | version 1.1 | 11/03/2025 | 07/05/2025 | No | Yes |
| Participant information sheet | version 1.1 | 11/03/2025 | 07/05/2025 | No | Yes |