ISRCTN31984588 https://doi.org/10.1186/ISRCTN31984588

# Patient and informal caregiver responses to symptoms during cancer treatment.

**Submission date**
01/12/2024

**Recruitment status**
Recruiting

**Registration date**
03/12/2024

**Overall study status**
Ongoing

**Last Edited**
04/12/2025

**Condition category**
Cancer

[X] 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
People with cancer frequently have to access urgent and emergency care services for complications of their disease or its treatment. Complications can be serious and are sometimes life-threatening. Little is known about how patients and their informal caregivers decide whether they need to use these services when they become unwell during cancer treatment. Few studies have explored how people with cancer choose between services and how accessing specialist services is influenced by the different ways in which they are set up. This study aims to address these gaps in our knowledge.

Who can participate?
People with cancer and their informal caregivers (e.g. family members or friends) who are at least 18 years old. Patient participants must be receiving care or treatment for an established cancer diagnosis at one of the study locations. The study will be conducted in two components. For the first component, patients must be receiving (or due to start) non-surgical cancer treatment, or have an ongoing complication of cancer or its treatment. For the second component, patient-participants must have accessed an urgent or emergency care service in the past two weeks for a suspected complication of cancer or its treatment. Informal caregivers can not take part on their own and they must be providing unpaid support to someone with cancer participating in the study.

What does the study involve?
In the first component, participants will be asked to use a diary to record any symptoms they experience over a 6-week period. Afterwards, they will be interviewed to explore what they thought was causing these symptoms and what actions they took in response. In the second component, participants who have recently used an urgent or emergency care service will be invited to an interview. This interview will explore why they decided to seek help and how they experienced gaining access to these services.

What are the possible benefits and risks of participating?
There are no direct benefits from taking part in this study. However, the study will identify what matters to people with cancer when they become unwell at home. We hope this will help cancer teams, service managers and health policy-makers to make improvements to services that will

benefit future patients. There is a risk that participants might find some of the topics in the interview upsetting.

Where is the study run from?
University of Southampton, UK

When is the study starting and how long is it expected to run for?
December 2023 to June 2026

Who is funding the study?
University Hospital Southampton NHS Foundation Trust, UK

Who is the main contact?
John Defty, jed1e16@soton.ac.uk

# Contact information

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

### Contact name
Mr John Defty

### ORCID ID
https://orcid.org/0000-0001-5338-2194

### Contact details
Clinical Academic Facility
A Level
South Academic Block
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD
-
jed1e16@soton.ac.uk

# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
342834

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number

92505

# Study information

### Scientific Title
Understanding how patients at risk of COMPlications of cancer and its treatment Appraise Symptoms and access urgent and emergency care Services: the COMPASS study

### Acronym
COMPASS

### Study objectives
How do people with cancer and their informal caregivers appraise symptoms suggestive of, and access urgent and emergency care services for, complications of cancer and its treatment?

### Ethics approval required
Ethics approval required

### Ethics approval(s)
approved 04/09/2024, Proportionate Review Sub-Committee of the Wales Research Ethics Committee 6 (Floor 4, Institute of Life Science 2, Swansea University, Singleton Park, Swansea, SA2 8PP, United Kingdom; +44 (0)29 2294 0911; Wales.REC6@wales.nhs.uk), ref: 24/WA/0245

### Study design
Multicentre qualitative multiple case study

### Primary study design
Observational

### Study type(s)
Other

### Health condition(s) or problem(s) studied
Patients at risk of, or who have accessed urgent and emergency care services for, complications of cancer and its treatment (and their informal caregivers).

### Interventions
Participants will be recruited to one of two study components: a prospective component or a retrospective component. In the prospective component, participants will be asked to use a semi-structured diary to record any symptoms they experience over 6 weeks before being invited to a semi-structured interview using their completed diary. In the retrospective component, participants who have recently used an urgent or emergency care service will be invited to a semi-structured interview, during which the interviewer and participants will draw and discuss a timeline of the events leading up to the decision to seek help.

### Intervention Type
Other

### Primary outcome(s)

The considerations, preferences and experiences that influence patients' and informal caregivers' decisions about appraising symptoms and accessing urgent and emergency care services for complications of cancer and its treatment measured using a semi-structured interview at one timepoint

### Key secondary outcome(s))
There are no secondary outcome measures

### Completion date
27/06/2026

## Eligibility

### Key inclusion criteria
Patient participant inclusion criteria: both study components
1. Age ≥18 years
2. Confirmed diagnosis of cancer (including cancer of unknown primary).

Patient participant inclusion criteria: prospective component only
People receiving (or due to start) non-surgical cancer treatment, or people with an ongoing complication of cancer or its treatment requiring self-management

Patient participant inclusion criteria: retrospective component only
Have accessed an urgent or emergency care service in the past 2 weeks for a suspected complication of cancer or its treatment

Informal caregiver inclusion criteria: both study components
1. Is a relative or friend of a patient meeting the patient participant inclusion criteria above
2. Meets the United Kingdom Department of Health and Social Care’s definition of an informal caregiver

### Participant type(s)
Carer, Patient

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 years

### Upper age limit
100 years

### Sex
All

### Total final enrolment
0

### Key exclusion criteria
Patient participant exclusion criteria: both study components
1. Age <18 years
2. No confirmed cancer diagnosis (including malignancy of unknown origin)
3. People receiving surgery as cancer treatment only
4. People resident at a nursing or care home, hospice or other institutional care setting
5. Prisoners or people supervised by representatives of His Majesty's Prison Service

Patient participant exclusion criteria: prospective component
1. People discharged from the care of an oncologist or haematologist
2. People in the last hours or days of life

### Date of first enrolment
11/12/2024

### Date of final enrolment
01/04/2026

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Salisbury NHS Foundation Trust**
Salisbury District Hospital
Odstock Road
Salisbury
England
SP2 8BJ

### Study participating centre
**University Hospitals Dorset NHS Foundation Trust**
Management Offices
Poole Hospital
Longfleet Road
Poole
England
BH15 2JB

# Sponsor information

**Organisation**
University of Southampton

**ROR**
https://ror.org/01ryk1543

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
University Hospital Southampton NHS Foundation Trust

**Alternative Name(s)**

**Funding Body Type**
Government organisation

**Funding Body Subtype**
Local government

**Location**
United Kingdom

# Results and Publications

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository at the University of Southampton (ePrints Soton; https://eprints.soton.ac.uk/). The dataset will include de-identified qualitative data and metadata. Data will be deposited after publication of findings and retained for a minimum of 10 years. Researchers with ethical approval may request access to the dataset by contacting the University of Southampton Library Research Data Service (eprints@soton.ac.uk) and completing a data request form. Access will be subject to a data access agreement. Written informed consent for anonymised data to be archived and shared for the purpose of future research will be sought from all study participants.

**IPD sharing plan summary**
Stored in publicly available repository

**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 |