

Patient and informal caregiver responses to symptoms during cancer treatment.

Submission date 01/12/2024	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/12/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 23/05/2025	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

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 February 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
342834

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

Protocol 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

Secondary study design

Case method study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

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 measure

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

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

19/12/2023

Completion date

11/02/2026

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)

Patient, Carer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

28-38 patient participants.

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

07/12/2025

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Salisbury NHS Foundation Trust

Salisbury District Hospital

Odstock Road

Salisbury

United Kingdom

SP2 8BJ

Study participating centre

University Hospitals Dorset NHS Foundation Trust

Management Offices

Poole Hospital

Longfleet Road

Poole

United Kingdom
BH15 2JB

Sponsor information

Organisation

University of Southampton

Sponsor details

Research Integrity and Governance
Building 37
University Road
Highfield
Southampton
England
United Kingdom
SO17 1BJ
+44 (0)23 8059 5058
rgoinfo@soton.ac.uk

Sponsor type

University/education

Website

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

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

Publication and dissemination plan

Planned publication in peer-reviewed journals and conference presentations

Intention to publish date

11/02/2027

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