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Integrated short-term palliative rehabilitation in incurable cancer

Submission date
24/04/2023

Recruitment status
Recruiting

Registration date
27/04/2023

Overall study status
Ongoing

Last Edited
22/10/2025

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Cancer is one of the main causes of illness, burden and death in Europe. The Joint Research Centre (JRC) of the EU estimated 2.7 million new cancer cases. For all cancers, between 53-79% of men and 41-62% of women are diagnosed with incurable disease. Their cancer treatment is life-prolonging but will not cure the disease.
Cancer is also a major and growing contributor to disability (loss of function). Recent global estimates suggest a loss of 382 disability-adjusted life years per 1000 individuals. Disability is a poorly recognised and undertreated consequence of incurable cancer. Over time, loss of function results in people not being able to continue with valued roles and routines, to manage usual household and social activities, and to self-care. One-third of adults with cancer require assistance to perform basic activities like washing and dressing, and half need help with extended activities like shopping and transportation. Disability reduces quality of life and well-being. Disability related to daily activity is closely related to unplanned hospital admissions and mortality.
Palliative rehabilitation empowers people with incurable conditions to actively manage their condition themselves, enabling them to live fully and enjoy the best health-related quality of life possible, including cancer towards the end of life. It aims to reduce symptoms and help people to stay independent and socially active. WHO policy on Universal Health Coverage states both rehabilitation and palliative care as essential, quality health services. It recommends they be integrated within and between primary, secondary, and tertiary health systems using a multi-professional workforce. While integrated rehabilitation has been achieved for people with chronic respiratory, cardiac and stroke conditions, this is not the case for people with cancer, especially those living with incurable disease. Access to palliative care services has increased but access to rehabilitation remains varied.

In this study, we are evaluating a rehabilitation intervention that has been designed to meet the needs of people living with advanced cancer. The study is taking place in countries across Europe, and we plan to recruit 340 patients from hospitals. We aim to find out if and how the rehabilitation intervention affects the people who take part in the study. We will also study how it fits in with current healthcare services.

Who can participate?
This study is suitable for patients aged 18 or over, diagnosed with advanced solid cancer: lung, colorectal, breast, prostate or other, irrespective of timing in relation to any oncology or palliative care treatments.

What does the study involve?
After signing the informed consent, the participation in this trial will last 16 weeks. Participation in this trial is voluntary and the participants can withdraw any time.
During the first face to face visit, participants will be randomly allocated to receive either INSPIRE rehabilitation intervention + usual care or usual care only. The random allocation will be done using a software maintained by the King's Clinical Trials Unit.
The trial schedule depends on group allocation:
Participants allocated to usual care only will be asked to complete questionnaires at weeks 4, 8 and 16 either on their own, with a help of a friend or family member, or with the researcher over the telephone or in person. It should take 30 – 45 minutes to compete all the questions.
Participants allocated to the INSPIRE rehabilitation + usual care will be offered up to 3 rehabilitation visits in addition to the questionnaire completion at weeks 4, 8 and 16. Each visit will last 30 -90 minutes.
- 1st rehabilitation visit will be face to face and will be scheduled no later than 14 days after joining the trial. During this visit, a rehabilitation action plan will be put together.
- 2nd rehabilitation will be scheduled around 4 weeks, but no later than 5 weeks after joining the trial.
- 3rd rehabilitation visit will be scheduled around 6 weeks, but no later than 7 weeks after joining the trial.
Both visits 2 and 3 can be face to face, via telephone or via video call and participants will have the opportunity to review and, if needed, change their rehabilitation action plan.
There won't be any changes in usual care for participants that have been allocated to the rehabilitation intervention group.
Participants allocated to the INSPIRE rehabilitation intervention may also be invited to an optional one-to-one interview with a member of a research team. The interview will last around 30-60 minutes
At the week 28 the research team will look at the participants medical notes to see how they're getting on; however participants will not need to do anything at this time.

The trial team will collect participants' medical history and demographic data; however demographic data will be anonymised and only year of birth and initials will be shared with the research teams. All data will be stored on a password-protected database to which only authorised individuals will have access.

What are the possible benefits and risks of participating?
The study is designed to help us understand if the rehabilitation intervention can benefit people living with advanced cancer. This is a very low risk study. This study will require attending appointments and complete questionnaires which might be tiring for some people. It is not yet clear if taking part in this study will be directly beneficial for the study participants. however, taking part should help to improve future care and research, to help care for people with similar conditions in the future.

Where is the study run from?
INSPIRE is coordinated by King's College London (UK) with centres in the UK, Italy, Denmark, Norway, and France.

When is the study starting and how long is it expected to run for?
September 2022 to August 2026

Who is funding the study?
Funding to conduct the trial in the European Union is provided by HORIZON-HLTH-2021-DISEASE-04. In the UK this study is funded by UKRI Innovate (UKRI Reference Number: 10047799)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
328722

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 328722

Study information

Scientific Title

Integrated Short-term Palliative Rehabilitation to improve quality of life and equitable care access in incurable cancer: A multi-national randomised controlled trial.

Acronym
INSPIRE

Study objectives
Palliative rehabilitation in addition to usual care is more effective than usual care at improving health-related quality of life in patients with incurable solid cancer

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multinational parallel group randomized controlled assessor blind superiority trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Advanced incurable solid cancer: lung, colorectal, breast, prostate, etc.

Interventions
The intervention being tested is Integrated Short-term Palliative Rehabilitation.

It comprises up to 3 manualised sessions (face to face and/or remotely (via telephone or video-conference) delivered by a rehabilitation practitioner (typically a physiotherapist or occupational therapist).
Core components focus on (i) self-management of symptoms, (ii) physical activities and fitness, and (iii) social participation, with explicit use of behaviour change techniques with goal setting and action planning.
The rehabilitation practitioner works in partnership with the person with incurable cancer, and those important to them, to support and optimise their function. Sessions focus on outcomes each person has said are important to them. The rehabilitation practitioner attends to practical, physical, emotional, psychological, and existential concerns impacting on function, either directly within the intervention or indirectly through onward referral. The intervention allows for individual tailoring and flexibility in location, timing and frequency of sessions and content over a 7-week intervention period. Participants can receive a minimum of two rehabilitation sessions and a maximum of three rehabilitation sessions.
It is delivered in addition to any usual services delivered by the participant's oncology team and palliative care team.

The randomisation ration is 1:1 (palliative rehabilitation + usual care : usual care only)

Intervention Type
Other

Primary outcome(s)
Health related quality of life - Functional Assessment of Cancer Therapy (FACT) General scale at 8 weeks

Key secondary outcome(s))
1. Functional Assessment of Cancer Therapy (FACT) General scale at 4 and 16 weeks
2. Disability - World Health Organization Disability Assessment Schedule (WHODAS 2.0) at 8 and 16 weeks
3. Symptoms- Palliative Outcomes Scale – Symptoms (POS-S) at 8 and 16 weeks
4. Goal attainment- Goal attainment scale (GAS-Light) at 8 and 16 weeks
5. Client Service Receipt Inventory at 8 and 16 weeks

Completion date
31/08/2026

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Diagnosis of incurable solid cancer: lung, colorectal, breast, prostate or other, irrespective of timing in relation to any oncology or palliative care treatments
3. Eastern Cooperative Oncology Group performance status 2-3
4. Able to provide informed consent and complete trial assessments in available languages.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Blood cancers: Leukaemia, Lymphoma, Myelodysplastic Syndromes (MDS), Myeloproliferative Disorder (MPD), Multiple Myeloma
2. Currently receiving specialist rehabilitation* for their cancer or co-morbidity-related dysfunction, or received within the two weeks prior to consent
3. Clinician rated prognosis of less than 3 months

Date of first enrolment

03/10/2023

Date of final enrolment
28/02/2026

Locations

Countries of recruitment
United Kingdom

England

Czech Republic

Denmark

France

Italy

Norway

Study participating centre
King's College Hospital
Denmark Hill
London
United Kingdom
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Study participating centre
Hospices Civils de Lyon
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Study participating centre
Fondazione IRCCS Istituto Nazionale dei Tumori
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20133

Study participating centre
Azienda Unità Sanitaria Locale – IRCCS di Reggio Emilia
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42122

Study participating centre
Fonden for Almen Praksis
Dampfærgevej 22
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Denmark
2100

Study participating centre
University of Bergen
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Norway
5007

Study participating centre
Guy's and St Thomas' Hospitals
Trust Offices
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Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre
York and Scarborough Teaching Hospitals NHS Foundation Trust
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Wigginton Road
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100 00

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
HORIZON EUROPE Framework Programme

Alternative Name(s)
Horizon Europe, Horizon Europe Programme, Framework Programme, Horizon Europe, EU Framework Programme, Horizon

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location

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?
Protocol file	version 1.0	17/11/2023	25/03/2024	No	No
Protocol file	version 2.0	14/05/2024	22/10/2025	No	No
Statistical Analysis Plan	version 1.0	30/10/2024	22/10/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes