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ACTION: cancer patient involvement in medical decision making

Submission date 03/10/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/10/2014	**Overall study status** Completed	
Last Edited 16/12/2022	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-a-new-way-to-help-people-with-advanced-cancer-plan-their-care-now-and-in-the-future-action

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
17231

Study information

Scientific Title

ACTION: a phase III multicentre cluster randomised clinical trial to assess whether the 'Respecting Choices Program' improves quality of life and symptoms of patients with advanced cancer

Acronym
ACTION

Study objectives
The overall hypothesis for the ACTION study is that formalised advance care planning significantly improves quality of life and reduces symptoms of patients with advanced cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/NW/1189; First MREC approval date 21/08/2014

Study design
Randomised; Interventional; Design type: Process of Care

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Cancer; Subtopic: Colorectal Cancer, Lung Cancer; Disease: Colon, Lung (small cell), Lung (non-small cell)

Interventions
The ACTION study is a cluster randomised control trial in which potential participants are randomised in groups (i.e. the group is randomised not the individual). In this case, the hospitals taking part in the study are treated as the cluster of patients and randomised as a unit.
Pairs of comparable hospitals have been randomised at the start of the study to provide either advance care planning (in the intervention hospitals) or 'standard care' (in the control hospitals). In this study, only the intervention hospitals will be exposed to the 'Respecting Choices Program' but it is acknowledged that other advance care planning activities may take place in the control hospitals as part of 'standard care'. The 'Respecting Choices Program' is a formalised model of advance care planning developed and currently being used in the United States and Australia. In this programme, a trained 'Respecting Choices Facilitator' invites patients to reflect on their personal goals, values and beliefs, to discuss and document their choices regarding their future treatment and care and to nominate someone who they may wish to be consulted about their treatment or care if they are not able to make decisions for themselves. After consenting to take part in the study, participants in the intervention hospitals are invited to take part in two advance care planning interviews with a trained 'Respecting Choices' facilitator in a location convenient to the patient. Patients will continue to be under the care of their health care team while on the study and after their involvement in the study has ended.

Intervention Type

Other

Phase
Phase III

Primary outcome(s)
Quality of life and symptoms; Timepoint(s): Baseline, 10-12 and 18-20 weeks (both control and intervention group)

Key secondary outcome(s))
1. Coping with their illness; Timepoint(s): Baseline, 10-12 and 18-20 weeks (both control and intervention group)
2. Decisional Quality and Patient Activation; Timepoint(s): Baseline, 10-12 and 18-20 weeks (both control and intervention)
3. Satisfaction with care; Timepoint(s): Baseline, 10-12 and 18-20 weeks (both control and intervention group)
4. Satisfaction with the intervention; Timepoint(s): 10-12 and 18-20 weeks (intervention group only)

Completion date
30/11/2018

Eligibility

Key inclusion criteria
Adult patients with advanced stages of lung or colorectal cancer. Patients need to have an estimated life expectancy of at least three months. The patients will be under the care of the oncologist at the participating hospitals.

Histologically confirmed diagnosis of:
1. Lung cancer:
2. Small cell extensive disease/ Stage III or IV*
3. Nonsmall cell stage III or IV*
4. Colorectal cancer: Stage IV *
*according to 7th edition of TNM classification and staging system
5. Written informed consent to participate
6. World Health Organisation performance status of 3 or under

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
1117

Key exclusion criteria
1. Age less than 18 years
2. Unable to provide consent
3. Unable to complete questionnaire in country's language
4. Less than 3 months anticipated life expectancy
5. Taking part in a research study that is evaluating palliative care services or communication strategies

Date of first enrolment
01/11/2014

Date of final enrolment
01/06/2018

Locations

Countries of recruitment
United Kingdom

England

Belgium

Denmark

Italy

Netherlands

Slovenia

Study participating centre
Lancaster University
Lancaster
United Kingdom
LA1 4YT

Study participating centre
Ikazia Hospital
Montessoriweg 1
Rotterdam
Netherlands
3083 AN

Study participating centre
Reinier de Graaf Hospital
Reinier de Graafweg 5
Delft
Netherlands
2625 AD

Sponsor information

Organisation
Lancaster University (UK)

ROR
https://ror.org/04f2nsd36

Funder(s)

Funder type
Government

Funder Name
Seventh Framework Programme

Alternative Name(s)
EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The current 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?
Results article	focus group results	31/10/2019	04/11/2019	Yes	No
Results article	results	13/11/2020	02/12/2020	Yes	No
Results article	Healthcare use and healthcare costs	14/12/2022	16/12/2022	Yes	No
Protocol article	protocol	08/04/2016		Yes	No
HRA research summary			28/06/2023	No	No
Other publications	coping strategies of patients	01/02/2020	07/10/2020	Yes	No
Other publications	serious adverse event reporting procedures	20/01/2021	22/01/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results				No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes