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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

Study website
http://www.action-acp.eu/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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)

Overall study start date
01/11/2014

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

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 1360; UK Sample Size: 272

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
Belgium

Denmark

England

Italy

Netherlands

Slovenia

United Kingdom

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)

Sponsor details
Research Support Office B58, Bowland Main
Bailrigg
Lancaster
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United Kingdom
LA1 4YT

Sponsor type
University/education

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

Publication and dissemination plan
Planned publication in a high level peer reviewed journal towards the end of 2018 or early 2019.

Intention to publish date

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?
Plain English results				No	Yes
Protocol article	protocol	08/04/2016		Yes	No
Results article	focus group results	31/10/2019	04/11/2019	Yes	No
Other publications	coping strategies of patients	01/02/2020	07/10/2020	Yes	No
Results article	results	13/11/2020	02/12/2020	Yes	No
Other publications	serious adverse event reporting procedures	20/01/2021	22/01/2021	Yes	No

Results article	Healthcare use and healthcare costs	14/12/2022	16/12/2022	Yes	No
HRA research summary			28/06/2023	No	No