ISRCTN75905964 https://doi.org/10.1186/ISRCTN75905964

SMaRT Oncology-3: a two-arm parallel group randomised controlled trial to determine the efficacy of adding a complex intervention for major depressive disorder ("Depression Care for People with Lung Cancer") to usual care, compared to usual care alone in patients with lung cancer

Submission date
18/11/2008

Recruitment status
No longer recruiting

Registration date
28/11/2008

Overall study status
Completed

Last Edited
26/10/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-treating-depression-people-lung-cancer-smart-oncology-3

Contact information

Type(s)
Scientific

Contact name
Prof Michael Sharpe

Contact details
School of Molecular and Clinical Medicine
The University of Edinburgh
Kennedy Tower
Royal Edinburgh Hospital
Edinburgh
United Kingdom
EH10 5HF
+44 (0)131 537 6672
michael.sharpe@ed.ac.uk

Additional identifiers

Protocol serial number
v1.0 25.09.08

Study information

Scientific Title
SMaRT Oncology-3: a two-arm parallel group randomised controlled trial to determine the efficacy of adding a complex intervention for major depressive disorder ("Depression Care for People with Lung Cancer") to usual care, compared to usual care alone in patients with lung cancer

Acronym
SMaRT (Symptom Management Research Trials)

Study objectives
Supplementing usual care with "Depression Care for People with Lung Cancer" will improve the following over eight months (32 weeks):
1. Depressive symptoms
2. Other symptoms (pain, fatigue, anxiety)
3. Functioning
4. Quality of life
5. Satisfaction with depression care

The pilot study for this trial can be found on the ISRCTN Register under ISRCTN16242820. In addition to this, a related trial SMaRT Oncology-2 is can also be found on the ISRCTN Register under ISRCTN40568538.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Scotland A Research Ethics Committee on 23/10/2008 (ref: 08/MRE00/95)

Primary study design
Interventional

Study design
Two-arm parallel-group randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Depression in patients with cancer

Interventions
Patients will be randomised to receive 'usual care' or 'usual care' plus "Depression Care for People with Lung Cancer". "Depression Care for People with Lung Cancer" is a complex

intervention which includes education on depression and its treatments, and a problem solving treatment. It is delivered by specially trained cancer nurses supervised by psychiatrists. A maximum of 10 sessions over 16 weeks will be given, followed by monthly follow-up telephone conversations for a further 4 months. Sessions last 30 minutes to 1 hour.

Details of Joint Sponsor:
NHS Lothian - University Hospitals Division (UK)
Research and Development Office
Royal Infirmary of Edinburgh
51 Little France Crescent
Edinburgh EH16 4SA
United Kingdom

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Average depression severity, assessed using Symptom Checklist (SCL)-20D scores, collected every four weeks over 32 weeks.

Key secondary outcome(s)
The following will be assessed every four weeks over 32 weeks:
1. Severity of anxiety symptoms, measured by the Symptom Checklist (SCL)-10A
2. Severity of pain and fatigue, measured by the relevant symptom scales of the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire for Cancer patients (EORTC QLQ-C30)
3. Physical, social and role functioning, and overall health and quality of life measured by the relevant scales of the EORTC QLQ-C30
4. Patient's satisfaction with depression care, measured by a 5-point Likert scale item developed specifically for the trial

Completion date
01/07/2011

Eligibility

Key inclusion criteria
1. Both males and females, aged 18 or over
2. Have a diagnosis of lung cancer
3. Have a predicted survival, estimated by their cancer specialist, of three months or more
4. Have symptoms which meet the Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) criteria for major depressive disorder (MDD), with symptoms of the current major depressive episode (MDE) present for four weeks or more using the inclusive approach to diagnosis

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
142

Key exclusion criteria
1. Unable to provide informed consent to participate
2. The episode of depression is chronic (defined as a history of continuous depression for at least two years)
3. Judged to require urgent psychiatric care
4. Receiving active psychiatric or psychological treatment from specialist mental health services
5. Cognitive impairment or communication difficulties (including inability to adequately understand verbal explanations or written information in English) which are incompatible with the intervention
6. Known cerebral metastases
7. Unable to participate regularly in treatment sessions
8. The intervention is judged to be inappropriate due to a medical condition which requires alternative treatment
9. The intervention is judged to be inappropriate due to a psychiatric condition which requires alternative treatment (psychotic illness, bipolar affective disorder, obsessive compulsive disorder, substance abuse or dependence)
10. Participation in the trial is judged to be inappropriate on other clinical grounds

N.B. Patients receiving active cancer treatments will not be excluded unless they fulfil one or more of the exclusion criteria listed above.

Date of first enrolment
01/12/2008

Date of final enrolment
01/07/2011

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
School of Molecular and Clinical Medicine
Edinburgh
United Kingdom
EH10 5HF

Sponsor information

Organisation
University of Edinburgh (UK)

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK)

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2014		Yes	No
Protocol article	protocol	30/09/2009		Yes	No
Plain English results			26/10/2022	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes