

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

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|----------------------------------------|---------------------------------------------------------------|--------------------------------------------------------------|
| Submission date 18/11/2008 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered |
| Registration date 28/11/2008 | Overall study status Completed | <input checked="" type="checkbox"/> Protocol |
| Last Edited 26/10/2022 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> 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

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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)

Study design

Two-arm parallel-group randomised controlled trial

Primary study design

Interventional

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/01nrxf90>

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 |