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# Better management of depression in cancer / Symptom Management Research Trials 3 Pilot

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 27/11/2007 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 13/12/2007 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 01/08/2012 | Cancer | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
NA

# Study information

## Scientific Title

## Acronym
SMaRT 3 Pilot

## Study objectives
A pilot trial to:
1: Test the feasibility and acceptability of procedures
2: Obtain data to inform the sample size calculation for the SMaRT Oncology-3 Trial

SMaRT Oncology-3 Trial: A two-arm parallel group randomised controlled trial to determine the efficacy of adding a multi-component intervention for major depressive disorder to usual care compared to usual care alone in cancer patients who have a limited life expectancy.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Lothian Local Research Ethics Committee approval granted on 13 September 2007 (ref: 07/S1104 /33)

## Study design
A two-arm parallel group randomised controlled pilot trial.

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Not specified

## Study type(s)
Not Specified

## 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
Cancer, major depressive disorder

## Interventions
Usual care:
The patients' general practitioner and oncologist will be informed of their diagnosis of MDD. Patients will then receive the usual clinical management of depression as currently practised.

Usual care supplemented with "Depression Care for People with Cancer":
In addition to the above Depression Care for People with Cancer will be implemented.

Components of Depression Care for People with Cancer:
1. Coordination of depression care and provision of information to all relevant health professionals
2. Brief psychological intervention for a maximum of ten sessions over a three-month period including education about depression and its management (behavioural activation and antidepressant medication) and problem-solving training
3. Monthly active follow-up by telephone for a further three-month period
4. Advice to general practitioner regarding the prescription of antidepressant medication

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
Acceptability and feasibility of the trial procedures

### Secondary outcome measures
The following data will be collected at baseline, 4, 8, 12, 16, 20 and 24 weeks:
1. Hopkin's Symptom Checklist Depression Scale (SCL-20)
2. European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-C30
3. EuroQuol-5D
4. Satisfaction with depression care item

### Overall study start date
03/12/2007

### Completion date
28/02/2008

## Eligibility

### Key inclusion criteria
1. Have a diagnosis of cancer
2. Be aged 18 or over
3. Be under specialist oncology care
4. Have a predicted survival, estimated by their cancer specialist, of between three and twelve months
5. Have symptoms which meet the Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) criteria for Major Depressive Disorder (MDD) (using the inclusive approach to diagnosis)

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
10-20

### Key exclusion criteria
1. Unable to provide informed consent to participate
2. Episode of MDD 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 which are incompatible with the intervention
6. Known cerebral metastases
7. Unable to attend regularly for treatment sessions
8. Intervention is judged to be inappropriate due to a medical condition which requires alternative treatment
9. 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 clinical grounds

### Date of first enrolment
03/12/2007

### Date of final enrolment
28/02/2008

## Locations

### Countries of recruitment
Scotland

United Kingdom

### Study participating centre
**Psychological Medicine & Symptoms Research Group**
Edinburgh
United Kingdom
EH10 5HF

# Sponsor information

### Organisation
University of Edinburgh, Lothian Health Board, University Hospitals Division (UK)

### Sponsor details
c/o Dr Marise Bucukoglu
Clinical Trials and Research Governance Manager
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The Queen's Medical Research Institute
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### Sponsor type
Hospital/treatment centre

### Website
http://www.ed.ac.uk/

### ROR
https://ror.org/01nrxwf90

# Funder(s)

### Funder type
Charity

### Funder Name
Cancer Research UK (ref: C5547/A7375)

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

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Other non-profit organizations

### Location
United Kingdom

# Results and Publications

## Publication and dissemination plan
Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary
Not provided at time of registration

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/09/2009 | | Yes | No |