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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

Protocol serial number
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

Study type(s)

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(s)
Acceptability and feasibility of the trial procedures

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

Scotland

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)

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, 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

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2009		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes