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Multi-component nurse delivered intervention for major depressive disorder in patients with cancer

Submission date	Recruitment status	[ ] Prospectively registered
22/08/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/01/2012	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Michael Sharpe

Contact details
University of Edinburgh
Division of Psychiatry
Kennedy Tower
Royal Edinburgh Hospital
Edinburgh
United Kingdom
EH10 5HF
+44 (0)131 537 6672
michael.sharpe@ed.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
SMaRT oncology 1

Study objectives
The supplementation of optimised usual care with a nurse delivered multifactorial intervention will be effective and more cost-effective than usual care alone in relieving major depressive disorder in patients attending an oncology outpatient clinic with a diagnosis of cancer and comorbid major depression.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cancer and depression

Interventions
Both groups will receive optimised usual care i.e. current practice in the Edinburgh Cancer Centre. In addition, the GP and Oncologist will be informed that the patient has major depression and asked to manage their care as normal. General guidance on the management of major depression will be given. A minority may be referred to specialist services. One group will, in addition, receive a nurse-delivered psychiatrist-supervised multi-component intervention. This intervention is based upon a case-management approach. It aims to empower the patient in

taking an active approach to the management of their depressive disorder and includes both training in advanced coping skills and antidepressant medication as prescribed by the patients GP.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The principal outcome measure will be a 50% reduction in the SCL-20 depressive symptoms score from baseline.

Secondary outcome measures
Secondary measures will be:
1. Mean depression scores from the SCL-20
2. Remission specified as an SCL-20 score of <0.75
3. The presence of major depressive disorder assessed by SCID diagnostic interview

Subsidiary outcome measures will be:
1. Quality of life measured on the World Health Organisation (WHO) EQ-5D
2. EORTC-QLQ-C30
3. Anxiety measured on the 10 anxiety items of the SCL-90
4. A measure of self-efficacy, coping and social support
5. An estimate of the direct health care costs measured by case note review and patient questionnaire

The outcomes will be measured at 3, 6 and 12 months

Overall study start date
06/10/2003

Completion date
30/06/2006

Eligibility

Key inclusion criteria
Patients attending Edinburgh Cancer Centre identified through a screening process or by referral and noted to have:
1. Definite or probable major depressive disorder on Structured Clinical Interview for Depression (SCID) interview
2. SCL-20 depression score of at least 1.72
3. A diagnosis of cancer

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
200

Key exclusion criteria
Predicted survival less than 6 months; another complicating and uncontrolled medical problem or where antidepressants are contraindicated; too ill to participate in treatment due to ongoing cancer therapy; complicating major psychiatric diagnosis or an alcohol or substance misuse problem; chronic depression; under active treatment for their depression; judged to be in need of urgent psychiatric treatment; unable to communicate adequately due to language problems or cognitive impairment; unable to travel to centre for treatment.

Date of first enrolment
06/10/2003

Date of final enrolment
30/06/2006

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University of Edinburgh
Edinburgh
United Kingdom
EH10 5HF

Sponsor information

Organisation
University of Edinburgh (UK)

Sponsor details
Queen's Medical Research Institute
47 Little France Crescent
Edinburgh
Scotland

United Kingdom
EH16 4TJ
+44 (0)131 242 9253
paul.mcguire@ed.ac.uk

Sponsor type
University/education

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK) (ref: C5547/A5576)

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?
Other publications	preliminary analysis	26/01/2004		Yes	No
Results article	results	05/07/2008		Yes	No