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

Submission date
22/08/2005

Registration date
15/09/2005

Last Edited
18/01/2012

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

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

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
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

Scotland

Study participating centre
University of Edinburgh
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) (ref: C5547/A5576)

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	05/07/2008		Yes	No
Other publications	preliminary analysis	26/01/2004		Yes	No