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

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

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

Prof Michael Sharpe

#### Contact details

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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

# 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              |