

# Managing social difficulties in routine oncology practice

<b>Submission date</b> 12/05/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/05/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/03/2016	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Ms Emma Ingleson

**Contact details**  
Psychosocial Oncology and Clinical Practice Research Group  
Beckett Street  
Leeds  
United Kingdom  
LS9 7TF

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
7042

## Study information

**Scientific Title**

Pilot study to assess provision of simple support services information versus standard care in managing social difficulties in routine oncology practice

### **Study objectives**

The primary objective of this study is to assess whether provision of information on support services can enhance patient well-being compared to standard practice. Specific aims are to develop and evaluate a Support Services Information Pack (SSIP) for patients, investigate the impact of this information provision on the process of care and patient well-being, and provide estimates of the effect size of this intervention in a future randomised trial. The main hypothesis is that simple information provision will improve detection of social difficulties, lead to a change in the process of care, lead to an increase in support accessed and an enhancement of patient well-being compared to standard care.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Leeds (Central) Research Ethics Committee, 11/05/2009, ref: 09/H1313/4

### **Study design**

Single centre randomised interventional treatment trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Other

### **Study type(s)**

Treatment

### **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**

Topic: National Cancer Research Network; Subtopic: All Cancers/Misc Sites; Disease: Bone, Head and Neck, Myeloma

### **Interventions**

All patients on the study are asked to complete baseline measures (recording of an out-patient review consultation with their doctor and four questionnaires). Patients are then randomised into an intervention (treatment) arm, or a control arm. Those in the intervention arm will be provided with a Support Services Information Pack. Those in the control arm receive standard care (i.e. no additional information or interventions to those already available from their clinical teams or within the hospital).

All patients, regardless of arm, are on the study for a further 3 consecutive out patient review appointments (4 in total including baseline). Therefore the length of follow-up varies depending on their treatment, but will be between 4 to 12 weeks, with some exceptions. Patients are also asked to participate in an exit interview which can be completed within 2 weeks of completion of their participation in the study.

Follow-up length: 4 months

Study entry: registration and one or more randomisations

29/08/2012: Please note that as of 27/07/2012 patient recruitment was stopped due to the objectives becoming inviable and a lack of participants and staff. Interviews with staff will continue until 31/12/2012.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

1. Cancer Rehabilitation Evaluation System-Short Form (CARES-SF)
2. Hospital Anxiety and Depression Scale (HADS)
3. Social Difficulties Inventory (SDI-21)

Measured at baseline (prior to any intervention) and end of study (after four months).

## **Secondary outcome measures**

1. Patient checklists: recording use of services at baseline and end of study
2. Nurse checklists: recording informal contact between nursing staff running the clinic and participating patients, measured at baseline, visits 1 - 3 and end of study
3. Audio recording: recording consultations that participating patients have with the doctors, measured at baseline, visits 1 - 3 and end of study

## **Overall study start date**

14/09/2009

## **Completion date**

31/12/2012

# **Eligibility**

## **Key inclusion criteria**

1. Be able to read and understand English
2. Have the capacity to give informed consent and complete the questionnaires
3. Not be participating in any other psychosocial studies
4. Be on active treatment having completed at least one cycle of chemotherapy and commenced radiotherapy
5. Be planning to continue treatment and attend the hospital for four consecutive appointments over 3 to 6 months
6. Male and female, lower age limit of 18 years

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned sample size: 60; UK sample size: 60

**Key exclusion criteria**

1. Does not meet inclusion criteria
2. Aged under 18 years

**Date of first enrolment**

14/09/2009

**Date of final enrolment**

31/12/2012

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

Psychosocial Oncology and Clinical Practice Research Group

Leeds

United Kingdom

LS9 7TF

**Sponsor information****Organisation**

University of Leeds (UK)

**Sponsor details**

Woodhouse Lane  
Leeds  
England  
United Kingdom  
LS2 9JT

**Sponsor type**

University/education

**Website**

<http://www.leeds.ac.uk/>

**ROR**

<https://ror.org/024mrxd33>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

Cancer Research UK (CRUK) (UK) (ref: C7775/A7424)

**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