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Managing social difficulties in routine oncology practice

Submission date	Recruitment status	[ ] Prospectively registered
12/05/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/05/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/03/2016	Cancer	[ ] 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