

Managing social difficulties in routine oncology practice

Submission date 12/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 16/03/2016	Condition category 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

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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 invariable and a lack of participants and staff. Interviews with staff will continue until 31/12/2012.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

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).

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

Psychosocial Oncology and Clinical Practice Research Group

Leeds

United Kingdom

LS9 7TF

Sponsor information

Organisation

University of Leeds (UK)

ROR

<https://ror.org/024mrx33>

Funder(s)

Funder type

Charity

Funder Name

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

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