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Quality of life (QOL) assessment in the care of individual cancer patients

Submission date 29/04/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 29/04/2010	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 16/10/2015	**Condition category** Cancer	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1460

Study information

Scientific Title
Quality of life (QOL) assessment in the care of individual cancer patients: a randomised interventional trial

Acronym
ATT (Attention Control Study)

Study objectives
To test the hypothesis that regular completion of quality of life (QOL) questionnaire, without feeding back results to oncologists, can help patients to explain their problems and can result in improved well being. The secondary aim of the study is to obtain a pure control and attention-control group for future studies, in which the oncologists will have the QOL information and can potentially influence the measured outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds East Research Ethics Committee approved on the 09/03/2004 (ref: 04/008)

Study design
Randomised interventional process of care trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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: All

Interventions
After the baseline visit, patients in the intervention group will be asked to complete the EORTC QLQ-C30 and HADS on a touch-screen (TS) computer while waiting to see a doctor. This will be done over 3 consecutive visits. The results will be printed and filed, but not given to their oncologists. The control group will receive their usual medical care. All consultations will be audio-taped and subjected to content analysis.

Follow up length: 6 months
Study entry: single randomisation only

Intervention Type
Other

Phase
Phase III

Primary outcome measure
1. Content of communication, measured at baseline and for a further three visits
2. Functional Assessment of Cancer Therapy General Scale (FACT-G), measured at baseline and at the end of the study

Secondary outcome measures
1. Other process measures (symptomatic drugs, tests, referrals), collected at baseline and for the next three visits
2. Patient-related outcomes (continuity of care and patient satisfaction), collected at baseline and at the end of the study
3. Descriptive information on patient views and attitudes regarding regular QOL data collection, collected at the end of the study

Overall study start date
01/03/2004

Completion date
30/11/2006

Eligibility

Key inclusion criteria
1. Newly diagnosed or relapsed patients with cancer starting chemotherapy or multimodality treatment
2. Expected to attend the clinic at least 3times after the initial baseline visit;
3. Able and willing to give informed consent
4. Not taking part in other QL studies run by the Unit
5. Able to read and understand English
6. Not exhibiting overt psychopathology or serious cognitive dysfunction which would impede their being able to take part in the study
7. Either sex, 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: 220

Key exclusion criteria
Does not meet the exclusion criteria

Date of first enrolment
01/03/2004

Date of final enrolment
30/11/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Psychosocial and Clinical Practice Research Group
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
University of Leeds (UK)

Sponsor details
Faculty of Medicine and Health
Leeds
England
United Kingdom
LS2 9JT
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FMHRO@leeds.ac.uk

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)

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