

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

Submission date 29/04/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/04/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/10/2015	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

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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 3 times 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