

Routine assessment versus standard care in managing social difficulties in routine oncology practice

Submission date 23/02/2011	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/02/2011	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/03/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-test-new-tool-how-people-cope-after-diagnosed-cancer>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

9698

Study information

Scientific Title

Pilot study to compare routine assessment versus standard care in managing social difficulties in routine oncology practice

Study objectives

The primary objective of this study is to explore the feasibility and effectiveness of implementing a programme of assessment for social difficulties, administered by trained nurses. Specific aims are to develop and evaluate a Nurse Training Package (NTP) to enable staff to carry out the assessment. This randomised pilot study will also investigate the impact of this assessment 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 a formal assessment of social difficulties will improve detection of issues, 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, 21/01/2011, ref: 11/H1313/3

Study design

Randomised interventional treatment

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details 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

Social Difficulties Inventory (SDI-21) Assessment: A formal assessment of the presence and severity of social difficulties, using the SDI-21 administered by a trained nurse. Follow up length: 3 months, study entry : registration and one or more randomisations

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

CARES-SF: Cancer Rehabilitation Evaluation System Short Form; Timepoints: Baseline and end of study

Secondary outcome measures

HADS: Hospital Anxiety and Depression Scale; Timepoints: Baseline and end of study

Overall study start date

04/04/2011

Completion date

30/09/2011

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

1. Be able to read and understand English
2. Have the capacity to give informed consent and complete the questionnaires and touch-screen assessment
3. Not have participated in the initial pilot study, assessing the role of information provision versus standard care
4. Not be participating in any other psychosocial studies
5. Be on active treatment having completed at least 1 cycle of chemotherapy and commenced radiotherapy
6. Be planning to continue treatment and attend the hospital for a minimum of two consecutive on-treatment review appointments and a minimum of one post-treatment follow-up appointment
7. Gender: Male and female
8. Lower Age Limit 18, no age limit specified

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

Patients who:

1. Cannot read and understand English
2. Are not on active treatment
3. Are already participating in an existing project being conducted by the Psychosocial Oncology and Clinical Practice Research Group
4. Participated in an initial pilot study, assessing the role of information provision versus standard care

Date of first enrolment

04/04/2011

Date of final enrolment

30/09/2011

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Psychosocial Oncology and Clinical Practice Research Group, Beckett Street

Leeds

United Kingdom

LS9 7TF

Sponsor information

Organisation

University of Leeds (UK)

Sponsor details

School of Medicine, The Worsley Medical & Dental Building, Clarendon Way

Leeds

England

United Kingdom

LS2 9NL

Sponsor type

University/education

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