ISRCTN70106175 https://doi.org/10.1186/ISRCTN70106175

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

Submission date 23/02/2011	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 23/02/2011	**Overall study status** Stopped	
Last Edited 16/03/2018	**Condition category** Cancer	

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
Mrs Emma Ingleson

Contact details
Psychosocial Oncology and Clinical Practice Research Group, Beckett Street
Leeds
United Kingdom
LS9 7TF
+44 (0) 113 3433459
e.j.ingleson@leeds.ac.uk

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. Bbe 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