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

23/02/2011	Stopped	<ul><li>[X] Prospectively registered</li><li>[] Protocol</li></ul>
Registration date	Overall study status	Statistical analysis plan
23/02/2011	Stopped	☐ Results
Last Edited	Condition category	☐ Individual participant data
16/03/2018	Cancer	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

Mrs Emma Ingleson

#### 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 touchscreen 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, Cancer Research UK (CRUK), 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