Evaluation of a palliative day care service for cancer survivors

Submission date	Recruitment status No longer recruiting	Prospectively registered		
21/09/2009		[_] Protocol		
Registration date	Overall study status	[] Statistical analysis plan		
09/11/2009	Completed	[X] Results		
Last Edited 27/11/2015	Condition category Cancer	[] Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 09/H0714/46

Study information

Scientific Title

A randomised controlled trial to evaluate a complex rehabilitative intervention for patients with advanced progressive recurrent cancer

Study objectives

The project aim is to assess whether a complex rehabilitative intervention, delivered in a voluntary sector hospice at the end of a course of treatment for recurrent cancer not considered to have been cured, offers a high value, cost-effective approach to care that is acceptable to patients and improves the patient experience compared with patients who have not yet accessed the intervention and are receiving usual care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Submitted to University College London Hospital A Research Ethics Committee, pending approval on 24th September 2009

Study design Randomised controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Quality of life

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

Palliative care for cancer survivors

Interventions

Patients who are selected for the intervention group will be offered immediate referral to the day therapy unit and will receive an individual systematic assessment by a senior member of the medical/nursing team. This will be followed by a process of goal setting, agreed with the patient, who is then referred to appropriate members of the multidisciplinary team selected on a case by case basis according to current need. Patients will have access to a range of individual and group therapies including access to medical outpatient clinics with palliative care specialists, counselling, physical rehabilitation, and alternative therapies (art therapy, aromatherpy, hydrotherapy).

Those randomised to usual care will join a waiting list and gain access to the intervention after follow-up.

Follow-up will be 3 months after baseline, and therefore duration of treatment will be up to 3 months in length, but will depend on how quickly the patient is referred to the service following randomisation (we expect minimum treatment duration of 6 weeks).

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

The psychological domain on the long form of Supportive Care Needs Survey (SCNS LF59), assessed at baseline and three months follow-up.

Secondary outcome measures

- 1. Continuity of care (Continuity of Care measure)
- 2. Psychological status (KD10)
- 3. Quality of life (EQ5D)
- 4. Physical function (measured by the ECOG)
- 5. Costs associated with the intervention and health service use will also be collected

Outcomes will be assessed at baseline and three months follow-up.

Overall study start date

31/10/2009

Completion date

31/12/2010

Eligibility

Key inclusion criteria

1. Patients who are attending Haematology and Breast Outpatient Departments at the Royal Free Hospital, London or University College London Hospitals

- 2. Patients with active, progressive recurrent malignant disease (first or subsequent remission)
- 3. Patients aged 18 years and above, either sex

4. Patients who are able to communicate effectively

Participant type(s) Patient

Age group Adult

Lower age limit 18 Years **Sex** Both

Target number of participants 240 patients in total across both sites

Key exclusion criteria

- 1. Patients who are considered to be cured of their malignant disease
- 2. Patients who have non-malignant disease only
- 3. Patients under 18 years old
- 4. Patients who are unable to feedback and communicate effectively

Date of first enrolment 31/10/2009

Date of final enrolment 31/12/2010

Locations

Countries of recruitment England

United Kingdom

Study participating centre Department Mental Health Sciences London United Kingdom NW3 2PF

Sponsor information

Organisation University College London (UCL) (UK)

Sponsor details Joint UCL, UCLH and RFH Biomedical Research Unit 1st Floor, Maple House 149 Tottenham Court Road

London England United Kingdom W1T 7NF **Sponsor type** University/education

Website http://www.ucl.ac.uk/

ROR https://ror.org/02jx3x895

Funder(s)

Funder type Government

Funder Name North London Cancer Network (UK)

Funder Name Department of Health (UK) - NHS Improvement Plan

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2013		Yes	No