ISRCTN22485853 https://doi.org/10.1186/ISRCTN22485853

Evaluation of a palliative day care service for cancer survivors

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Louise Jones

Contact details
Department Mental Health Sciences
Royal Free Hospital
Rowland Hill Street
London
United Kingdom
NW3 2PF

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