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

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Additional identifiers

Protocol serial number
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

Study type(s)
Quality of life

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

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
University College London (UCL) (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

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