

Evaluation of a palliative day care service for cancer survivors

Submission date 21/09/2009	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 09/11/2009	Overall study status Completed	☐ Statistical analysis plan ☒ 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

Contact name
Dr Louise Jones

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

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

Primary study design

Interventional

Study design

Randomised controlled trial

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, aromatherapy, 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