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A randomised controlled trial of occupational therapy in oncology: a pilot study

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 24/05/2012	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0192119065

Study information

Scientific Title

Study objectives
To identify whether occupational therapy intervention improves the mood, fatigue management and activities of daily living (ADL) performance of outpatient oncology patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

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
Cancer: All

Interventions
Intervention arms: Patients will receive a minimum of five sessions.
Session 1 - initial interview, general assessment and baseline assessments.
Session 2 - fatigue management/energy conservation session and equipment provision.
Session 3 - anxiety management/relaxation session.
Session 4 -fatigue/anxiety management session - check understanding and use of principals.
Session 5 - review progress.
Further sessions will be conducted if considered appropriate, up to a maximum of seven.

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
We aim to follow up two groups of patients at 6 and 12 weeks after randomisation and compare outcome.

Secondary outcome measures
Not provided at time of registration

Overall study start date
17/09/2002

Completion date
09/05/2003

Eligibility

Key inclusion criteria
All patients will be seen on their second or third clinic appointment.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Total number of subjects = 52

Key exclusion criteria
Living outside the hospital catchment area or refusal to consent.

Date of first enrolment
17/09/2002

Date of final enrolment
09/05/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Ageing and Disability Research Unit
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Queen's Medical Centre University Hospital NHS Trust - UK (NHS R&D Support Funding)

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	01/03/2006		Yes	No