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 	
Registration date	Overall study status	Statistical analysis plan	
12/09/2003	Completed	[X] Results	
Last Edited 24/05/2012	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 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