Adjuvant psychological therapy for families of children with cancer: a controlled trial.

Submission date 29/09/2006	Recruitment status Stopped	 Prospectively registered Protocol
Registration date 29/09/2006	Overall study status Stopped	 Statistical analysis plan Results
Last Edited 16/10/2012	Condition category Cancer	 Individual participant data Record updated in last year

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 N0258016631

Study information

Scientific Title

Study objectives To evaluate paediatric adjuvant psychological therapy in this paediatric population.

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) Treatment

Participant information sheet

Health condition(s) or problem(s) studied Cancer: All

Interventions Randomised test intervention vs no intervention controls (phase III).

Added 05/10/10: trial stopped in 2006 due to poor recruitment

Intervention Type Other

Phase Phase III

Primary outcome measure Quality of life

Secondary outcome measures Not provided at time of registration Overall study start date 01/03/1995

Completion date 01/04/2006

Reason abandoned (if study stopped) Participant recruitment issue

Eligibility

Key inclusion criteria 102 RMH patients. All new admissions to the paediatric unit aged between 4-16 years

Participant type(s) Patient

Age group Child

Lower age limit 4 Years

Upper age limit 16 Years

Sex Not Specified

Target number of participants 102

Key exclusion criteria 1. Non-English speaking 2. Extremely poor medical prognosis

Date of first enrolment 01/03/1995

Date of final enrolment 01/04/2006

Locations

Countries of recruitment England

United Kingdom

Study participating centre Psychological Medicine Sutton United Kingdom SM2 5PT

Sponsor information

Organisation Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details

The Department of Health, Richmond House, 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type Government

Website http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type Government

Funder Name The Royal Marsden NHS Foundation 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