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Reducing treatment related distress in children with leukaemia

Submission date 20/10/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 20/10/2011	**Overall study status** Completed	
Last Edited 04/04/2022	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-study-looking-at-way-of-reducing-distress-caused-by-treatment-for-leukaemia-in-children

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10216

Study information

Scientific Title
Does an interactive child-centred workshop reduce treatment-related distress and improve quality of life in children with leukaemia?

Study objectives
This is a prospective study in which children (n=120) aged between 7 and 12 years who have been treated for leukaemia at Royal Manchester Childrens Hospital will be invited to participate in a series of child-centred interactive workshops which use puzzles and games to teach children about basic human biology, leukaemia and its treatment. The aim of the study is to evaluate whether these workshops are able to reduce treatment-related distress and improve quality of life in these children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West 5 Haydock Park REC, 08/10/2010, ref: 10/H1010/45

Study design
Interventional prevention randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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
National Cancer Research Network: Paediatric Oncology, Disease: Leukaemia (acute), Leukaemia (acute myeloid), Leukaemia (acute lymphoblastic), Paediatrics

Interventions
The children will be randomised to an immediate group and a delayed control group. The immediate group will attend the workshops straight away, whilst the delayed group will serve as the controls and will attend the workshops after an 18 week interval. The child-centred interactive workshop will be delivered once weekly for 4 weeks. A series of standardised and validated questionnaires will be used to assess anxiety and fear of medical procedures, child quality of life, child emotional and behavioural functioning, the parental care-giving burden, and

self-efficacy in both groups before and after workshop attendance. The effectiveness of the workshops will be analysed using a multi-level growth curve modelling approach. The data collected will be coded to protect patient confidentiality. Participation in the study will not influence the clinical care of the patients enrolled on the study. Followed up afer 6 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Quality of life
2. Emotional and behavioural functioning

Theses are measured immediately before, immediately after intervention, at 12 weeks and at 6 months

Secondary outcome measures
1. Caregiving burden
2. Ffear of medical procedure
3. Self-efficacy

These are measured immediately before, immediately after intervention, at 12 weeks and at 6 months.

Overall study start date
02/01/2012

Completion date
01/01/2013

Eligibility

Key inclusion criteria
1. Patients aged between 7 and 12 years
2. Treated for leukaemia at Royal Manchester Children's Hospital
3. Parents must be able to receive and understand verbal and written information about the study and give written informed consent
4. Male and female participants

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
Planned Sample Size: 120; UK Sample Size: 120; Description: Two groups of 60, early and delayed intervention.

Total final enrolment
58

Key exclusion criteria
1. Age under 7 or over 12 years
2. Other types of maligant disease

Date of first enrolment
02/01/2012

Date of final enrolment
01/01/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Manchester Childrens Hospital
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
Central Manchester University Hospitals NHS Trust (UK)

Sponsor details
Genetic Medicine
Manchester Royal Infirmary
Oxford Road

Manchester
England
United Kingdom
M13 9WL

Sponsor type
Hospital/treatment centre

Website
http://www.cmft.nhs.uk/

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Government

Funder Name
National Institure for Health Research (NIHR) - Research for Patient Benefit (RfPB) (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results			04/04/2022	No	Yes