

# Reducing treatment related distress in children with leukaemia

<b>Submission date</b> 20/10/2011	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/10/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/04/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## 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

### Contact name

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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 after 6 months.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

1. Quality of life
2. Emotional and behavioural functioning

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

**Secondary outcome measures**

1. Caregiving burden
2. Fear 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 malignant 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 Institute 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?
<a href="#">Plain English results</a>			04/04/2022	No	Yes