

Reducing treatment related distress in children with leukaemia

Submission date 20/10/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/10/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 04/04/2022	Condition category 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

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Additional identifiers

Protocol serial number

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

Study type(s)

Prevention

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(s)

1. Quality of life
2. Emotional and behavioural functioning

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

7 years

Upper age limit

12 years

Sex

All

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

United Kingdom

England

Study participating centre

Royal Manchester Childrens Hospital

Manchester

United Kingdom

M13 9WL

Sponsor information

Organisation

Central Manchester University Hospitals NHS Trust (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

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