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The efficacy of an on-line coaching program focusing on the promotion of an active lifestyle in children after medical cancer treatment.

Submission date
05/02/2013

Recruitment status
No longer recruiting

Registration date
28/02/2013

Overall study status
Completed

Last Edited
01/11/2013

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Children with cancer often go through intensive and long-term treatments such as chemotherapy, radiation, surgical, or combined interventions. From the literature we know that these children have many problems after the therapy comes to an end such as: decreased bone density, obesity, lower quality of life, decreased stamina, physical inactivity, and fatigue. Also mentioned are specific motor performance problems (both fine and gross motor skills), cognitive, and social problems. Several authors propose that physical training and behavioral programs over an extended period of time are advisable for children after cancer therapy.
The goal of this study is to evaluate how well the COME ON, move on! program works in children who received medical treatment for cancer, compared to pediatric physical therapy treatments without intensive coaching through the Internet. This new intervention program focuses on short- and middle term participation in sports and games by using a one-year coaching program to encourage children and their parents to take on an active lifestyle after completing medical treatment. We believe that an active lifestyle will lead to better recovery and gradual improvement in motor performance, physical fitness, and quality of life, and want to see if this is the case.

Who can participate?
The intervention focuses on children aged 4-12 years. These children need help from their parents so these parents will be coached during the intervention program.

What does the study involve?
This study implies an improvement in care: at T0 a problem inventory will be conducted. During interaction with the child and the parents an intervention program will be determined. This program will focus on optimal tuning between burden and resilience, so therefore the extent of burden will be decreased.

What are the possible benefits and risks of participating?
Risks are not expected during the intervention due to regular evaluations of the recovery process and by detecting any eventual complications (e.g. recession) early.

Where is the study run from?
The Paediatric Physical Therapy Department of the Radboud University Nijmegen Medical Centre, the Netherlands

When is the study starting and how long is it expected to run for?
The study took place between May 2008 and May 2010.

Who is funding the study?
Roparun Foundation and Friends of the Radboud University Childrens Hospital in Nijmegen (Netherlands)

Who is the main contact?
Prof Maria Nijhuis van der Sanden
r.nijhuis@iq.umcn.nl

Contact information

Type(s)
Scientific

Contact name
Prof Maria Nijhuis van der Sanden

Contact details
114 Scientific Institute for Quality of healthcare
Radboud university of Nijmegen
PO box 9101
Nijmegen
Netherlands
6500 HB
r.nijhuis@iq.umcn.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ABR nr NL19315.091.07

Study information

Scientific Title

Acronym
COME ON move on!

Study objectives
The goal of this study is to test the greater efficacy of the COME ON, move on! program in children, who received medical treatment for cancer, compared to pediatric physical therapy treatments without intensive coaching by Internet. This new intervention program focuses on short and middle term increment of participation in sports and games by using a one-year coaching program to stimulate children and their parents to take on an active lifestyle after completing medical treatment. It is hypothesized that an active lifestyle will lead to better recovery and increment of motor performance, an increment in physical fitness, and quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
All study procedures were approved by the regional medical ethical committee from the Radboud University Medical Centre, ABR NL19315.091.07, CMO dossier 2007/171.

Study design
Explorative randomized controlled single-blinded study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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
Children aged 4-12 years who had finished their treatment for Acute Lymphoblastic Leukemia (ALL) or other types of cancer.

Interventions
In the COME ON, move on! program all children are coached individually for the period of one year to stimulate the start of a normal age-related lifestyle and to participate in daily activities, games and sports. The pediatric physical therapist in the UMC St Radboud will design a program with concrete goals and assignments, which fit with 1) the childs needs and ambitions, 2) the childs actual level and 3) the childs daily life and environment. The program will be performed at home in the childs own surroundings with or without additional pediatric physical therapy or other intervention. The exercise training will be adapted into normal daily activities of the child and the parents.
During the program (duration one year) the pediatric physical therapist from the UMC St

Radboud will regularly contact the child and the parents by means of an Internet website specially designed for the COME ON, move on! program. During the one-year coaching program there will be a switch from intensive coaching (weekly contact) to more and more autonomy and independence of the child towards resuming and maintaining a normal age-related lifestyle and participation in daily activities, games and sports. The control group will be referred to a pediatric physical therapist if indicated. At the moment referral to pediatric physical therapy for an assessment is not standard and functional problems are mostly detected after a few months. Therefore, both groups (the experimental and control group) profit from the study program.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The primary outcome variables are the degree of physical activity as measured with the actometer (the Techtrail) and the registered activities in the diary, converted to Metabolic Equivalents (METs) at T0,T1,T2 and T3. The difference in intra-individual changes will be compared between groups: a significant difference from 10% between T2 and T3 will be judged as clinically relevant.

Secondary outcome measures
The secondary outcome variables are the change in motor performance level (MABC), endurance level (BRUCE protocol), quality of life level (TAQOL child and parents), and the extent of participation in sports (sport questionnaire). The difference in intra-individual changes will be compared between the two groups. A significant difference of 10% between T2 and T3 will be judged as clinically relevant. The influence of background variables (disease, age, SES etc.) will be analyzed. Moreover, the presence of age-related reference-norms in the MABC, the BRUCE, and the TAPQOL allow comparison with the typical population.

Overall study start date
01/05/2008

Completion date
01/05/2010

Eligibility

Key inclusion criteria
Children aged 4-12 years, who completed the cancer therapy in the UMC St Radboud after informed consent from the parents. For this explorative study we expected to include 30 children (25 eligible each year, 30% informed consent).

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
Children in the palliative phase of treatment, children with brain tumors, children with an amputation of a limb, or children with a counter-indication for maximal effort, will be excluded.

Date of first enrolment
01/05/2008

Date of final enrolment
01/05/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
114 Scientific Institute for Quality of healthcare
Nijmegen
Netherlands
6500 HB

Sponsor information

Organisation
Radboud University Nijmegen Medical Centre, Scientific Institute for Quality of Healthcare (Netherlands)

Sponsor details
c/o Prof.dr. Maria WG Nijhuis-van der Sanden
114 Scientific Institute for Quality in Healthcare
Radboud University Nijmegen Medical Centre
PO Box 9101
Nijmegen

Netherlands
6500 HB
+31 24 3510137
r.nijhuis@iq.umcn.nl

Sponsor type
Research organisation

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
This study was an investigator initiated study funded by the Roparun Foundation http://www.roparun.nl

Funder Name
The website was funded by the Friends of the Radboud University Childrens Hospital in Nijmegen. http://www.mijnliefstewens.nl

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