

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	☐ Prospectively registered ☐ Protocol
Registration date 28/02/2013	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 01/11/2013	Condition category Cancer	☐ 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
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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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.

Primary study design

Interventional

Study design

Explorative randomized controlled single-blinded study

Study type(s)

Quality of life

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 child's needs and ambitions, 2) the child's actual level and 3) the child's daily life and environment. The program will be performed at home in the child's 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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

4 Years

Upper age limit

12 Years

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration