

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

Published: 14-01-2008

Last updated: 09-05-2024

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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Leukaemias
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON31168

### Source

ToetsingOnline

### Brief title

COME ON move on!

### Condition

- Leukaemias

### Synonym

late effects of treatment, survivors of childhood cancer

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud

**Source(s) of monetary or material Support:** RopaRun

## **Intervention**

**Keyword:** active lifestyle, Cancer, Children, Physical Fitness

## **Outcome measures**

### **Primary outcome**

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 (MET\*s) 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. The influence of background variables (disease, age, SES etc.) will be analyzed.

### **Secondary outcome**

The secondary outcome variables are the change in motor performance level (MABC), endurance level (BRUCE protocol), quality of life level (TAQOL child and parents), competence level (CBSK) 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, the TAPQOL and the CBSK allow comparison with the typical population. To test to which extend the oncologist refers these children without screening by the pediatric physical therapist, each child we see we will record if a referral had been given or

not. The percentage referrals will be compared to the outcome measurements from the standardized and norm referenced measurement instruments at T0.

## Study description

### Background summary

Children suffering from cancer often go through intensive and long-lasting therapy with chemo-, radiation-, surgical or combined interventions. From literature we know that these children have many problems after ending the therapy such as; decreased bone density, obesity, lower quality of life, decreased physical endurance, physical inactivity and fatigue. Moreover, specific motor performance problems (both fine and gross motor skills), cognitive and social problems are also mentioned. Several authors propose that physical training and behavioural programs during a longer period of time is advisable for children after cancer therapy.

To date there have been no controlled studies conducted focusing on the efficacy of training programs in children during or after the cancer therapy. In one recent controlled study during the maintenance phase of cancer therapy a significant increase in muscle force and gait skills was found in children with acute lymphoblastic leukemia (ALL), however their physical fitness was unchanged. A possible explanation is that during this phase of cancer therapy fitness recovery is not possible within four months. Another explanation is that fitness training was not included in the therapy plan in this study.

No other information is present concerning the efficacy of physical training in children receiving cancer therapy. From non-controlled studies in adults, we know that physical activity and training have a positive effect on physical fitness, the immune system and quality of life.

Therefore, it is relevant for cancer centers to offer structured continuing care for children after the medical cancer treatment is stopped. These programs need to be evidence based.

### Study objective

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, an increment in competence and quality of life.

## **Study design**

A randomized, controlled, single-blinded study in children aged 4-12 years, who completed the cancer therapy in the UMC St Radboud. All children will be informed orally and written by the pediatric oncologist during their visit to the outpatient clinic. After informed consent all children will be randomly assigned to the experimental or control group with stratification for the types of cancer (Acute Lymphatic Leukemia [ALL] versus other types of cancer) and for their age group ( 4-7 years versus 8-12 years). After the randomization the T0 measurement will be conducted and the outcomes will be used as a baseline measurement in both groups. For the experimental group these baseline measurements will be used to establish the pediatric physical therapy intervention plan, in the control group to define the indication for eventual referral. After four months an evaluation measurement (T1) will take place to test the efficacy of the level of activity and to interview the parents. In the experimental group this measurement will also be used to reset the training program.

After one year in both groups an evaluation measurement (T2) will be conducted, and another 6 months later after finishing the program a follow-up measurement (T3) will be conducted. Both measurements will be carried out by a researcher who is blinded for the treatment. Both groups will be tested in total four times in one-and-a-half year span: T0 t/m T3.

All anonymous demographic data will be stored in a database: date of birth, age at the start of the study, gender, and Social Economic Status (SES) of the parents. Relevant information about the disease history will be taken from the patient medical file (type of tumor, age, diagnosis, therapy, relevant complications in the treatment period). Moreover, the oncologists will make a not if he judged the pediatric physical therapy intervention and if referral was relevant or not.

At T0, T1, T2 en T3 the following will be measured; height and weight, the child\*s motor performance level (MABC test), endurance level (aerobic strength, BRUCE test), current daily physical activities (actometer), home activities which are registered in a diary, a quality of life questionnaire (TAPQOL), the competence experience scale for children (CBSK) and the child\*s participation in sports and games (questionnaire).

## **Intervention**

In the \*COME ON, move on!\* program all children are coached individually for the period of one year to stimulate the recommence 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. At this 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.

### **Study burden and risks**

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 extend of burden will be decreased. Risks are hardly to expect during the intervention due to regular evaluations of the recovery process and by detecting any eventual complications (eg. recession) early.

## **Contacts**

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## **Trial sites**

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Children (2-11 years)

### Inclusion criteria

Children (aged 4-12 years) who have finished the cancer treatment phase in the UMC St Radboud.

### 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.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Other

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2007
Enrollment:	60

Type:

Anticipated

## Ethics review

Approved WMO

Application type:

First submission

Review commission:

CMO regio Arnhem-Nijmegen (Nijmegen)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

**Register**

**ID**

CCMO

NL19315.091.07