**Trial Description**

**Title**

Effects of a targeted, individualized sports therapy program for childhood cancer patients on motor Performance


**Trial Acronym**

Escimo

**URL of the trial**

[---]*

**Brief Summary in Lay Language**

The aim of this study is to examine the effect of a 6-month targeted, individualized sports therapy program for childhood cancer patients on physiological, psychological and social parameters. The main objective is to determine the effect on motor performance. Therefore, 69 children will be included according to defined inclusion and exclusion criteria. The intervention group consists of childhood cancer patients participating in the sports program. The first control group includes patients not participating in the program while the second group contains healthy peers. Some changes in the study protocol (adding the second control group and therefore increasing the number of participants, reducing the number of secondary outcomes and adjusting the inclusion criteria) were made according to an amendment.

**Brief Summary in Scientific Language**

The aim of this non-randomized, controlled trial ist to examine the effect of a targeted, individualized sportstherapy within a representative sample of childhood cancer patients after inpatient, medical treatment. While patients of the intervention group take part in a 6-month targeted, individualized sports therapy program, patients of the control group do not attend any intervention. Healthy children (siblings and friends) serve as a second control group. Outcomes are motor performance, health-related quality of life and level of activity.

**Organizational Data**

- **DRKS-ID:** DRKS00004450

*PLEASE NOTE: This trial has been registered retrospectively.*
DRKS-ID: DRKS00004450
Date of Registration in DRKS: 2012/10/09
Date of Registration in Partner Registry or other Primary Registry: [---]*

Investigator Sponsored/Initiated Trial (IST/IIT): yes
Ethics Approval/Approval of the Ethics Committee: Approved
(leading) Ethics Committee Nr.: 40/2012, Ethikkommission der Deutschen Sporthochschule Köln

Secondary IDs

Health condition or Problem studied

- ICD10: C00-D48 - Neoplasms
- Free text: childhood cancer

Interventions/Observational Groups

- Arm 1: 6-month sports therapy program for childhood cancer patients after inpatient medical treatment (once a week, 60 minutes)
- Arm 2: childhood cancer patients; no intervention
- Arm 3: healthy children; no intervention

Characteristics

- Study Type: Interventional
- Study Type Non-Interventional: [---]*
- Allocation: Non-randomized controlled trial
- Blinding: [---]*
- Who is blinded: [---]*
- Control: Active control (effective treatment of control group), Control group receives no treatment
- Purpose: Supportive care
- Assignment: Parallel
- Phase: N/A
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): N/A
Study Type: **Interventional**
Study Type Non-Interventional: [---]*
Allocation: **Non-randomized controlled trial**
Blinding: [---]*
Who is blinded: [---]*
Control: **Active control (effective treatment of control group), Control group receives no treatment**
Purpose: **Supportive care**
Assignment: **Parallel**
Phase: **N/A**

Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

**Primary Outcome**

Motor performance of all study participants are examined using standardized motor test batteries (MOT 4-6; DMT 6-18) with study entry (baseline), after 3 month (only intervention group) and after 6 month.

**Secondary Outcome**

Health-related quality of life (KINDL-questionnaire and oncology module) and level of activity (modified MoMo-questionnaire) are examined with study entry (baseline), after 3 month (only intervention group) and after 6 month.

**Countries of recruitment**

- DE Germany

**Locations of Recruitment**

- Medical Center Kinderkrankenhaus Amsterdamer Straße, Köln

**Recruitment**

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/07/18**
- Target Sample Size: **69**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**
Inclusion Criteria

- **Gender:** Both, male and female
- **Minimum Age:** 4 Years
- **Maximum Age:** 17 Years

Additional Inclusion Criteria

IG and CG (1): oncological treatment, cessation of inpatient medical treatment, between four and seventeen years of age, diagnosis less than five years ago, hemoglobin and heart rate within normal range, no infections, medical clearance from the treating physician, informed consent from legal Guardian
CG (2): healthy children, matched pair (age and gender) to IG, informed consent from legal guardian

Exclusion criteria

specific stresses (according to the physicians advice), specific physiological and/or psychosocial impairments (according to the physicians advice)

Addresses

**Primary Sponsor**

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**Sources of Monetary or Material Support**

- **Institutional budget, no external funding (budget of sponsor/PI)**

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**Status**

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/03/31**

**Trial Publications, Results and other documents**
