FITstrong: The feasibility of an exercise program for children who survived cancer

| Submission date | Recruitment status No longer recruiting | Prospectively registered | | |
|-------------------|---|--|--|--|
| 05/09/2007 | | Protocol | | |
| Registration date | Overall study status | Statistical analysis plan | | |
| 05/09/2007 | Completed | [X] Results | | |
| Last Edited | Condition category | Individual participant data | | |
| 10/06/2021 | Cancer | | | |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr T. Takken

Contact details

University Medical Centre Utrecht (UMCU)/WKZ KB.02.056.0 Lundlaan 6 Utrecht Netherlands 3584EA +31 (0)30 250 4030 t.takken@umcutrecht.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

The feasibility of an exercise program for children who survived cancer: the FITStrong study

Acronym

FITstrong

Study objectives

Exercise training is a feasible method to improve fitness (peak oxygen uptake), muscle strength and fatigue in children who survived cancer.

Feasibility will be studied according to the number of performed training sessions and a structured interview with patients and training about their opinion on the training program.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from University Medical Center Utrecht (The Netherlands) on the 2nd April 2007 (ref: 06/303).

Study design

A 12 week aerobic and muscle strength training program (twice a week) compared with baseline training level

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Exercise in children who survived cancer

Interventions

Two times a week exercise training (45 minutes) starting with warm up, followed by muscle strength components and aerobic components and ended with a cool down. The participants have to perform home exercise two times per week, and at increasing muscle strength /endurance.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Feasibility of the program.

Timepoints:

t=0: baseline

t=1: after 12 weeks of training

t=2: 12 weeks follow-up

Secondary outcome measures

- 1. Peak oxygen uptake (VO2peak)
- 2. Muscle strength

Timepoints:

t=0: baseline

t=1: after 12 weeks of training

t=2: 12 weeks follow-up

Overall study start date

01/05/2007

Completion date

01/01/2008

Eligibility

Key inclusion criteria

1. 6 - 18 years of age

2. Between 0.5 and 1.5 years since final chemotherapy

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

Total final enrolment

16

Key exclusion criteria

Severe cardiomyopathy.

Date of first enrolment

01/05/2007

Date of final enrolment

01/01/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Centre Utrecht (UMCU)/WKZ

Utrecht Netherlands 3584EA

Sponsor information

Organisation

University Medical Centre Utrecht (UMCU) (The Netherlands)

Sponsor details

Wilhelmina Children's Hospital (WKZ)
Department Pediatric Fysiotherapy
Lundlaan 6
Amsterdam
Netherlands
3584 EA
+31 (0)30 250 4030
p.j.m.helders@umcutrecht.nl

Sponsor type

Hospital/treatment centre

Website

http://www.umcutrecht.nl/zorg/

ROR

https://ror.org/04pp8hn57

Funder(s)

Funder type

University/education

Funder Name

Scientific College of Physiotherapy (Wetenschappelijk College Fysiotherapie [WCF]) (The Netherlands)

Funder Name

RoPaRun Foundation (Stichting RoPaRun) (The Netherlands)

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

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-----------------|---------|--------------|------------|----------------|-----------------|
| Results article | | 01/04/2009 | 10/06/2021 | Yes | No |