Utrecht Spina Bifida And Graded Exercise (USAGE) Study part 2: Does training in ambulatory children with SB increase levels of physical fitness, energy cost of locomotion and daily physical activity?

Published: 21-10-2008
Last updated: 10-08-2024

Primary objective:To evaluate the effects of a training program on physical fitness, energy cost of locomotion and daily physical activity in ambulatory children and adolescents with Spina Bifida Secondary objectives: (1) evaluate physical fitness (...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders congenital
Study type	Interventional

Summary

ID

NL-OMON32469

Source
ToetsingOnline

Brief title
USAGE part 2

Condition

- Neurological disorders congenital

Synonym
Fitness and gaittraining in children with Spina Bifida

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Stichting BIO Kinderrevalidatie

Intervention

Keyword: Children with Spina Bifida, Energy cost of locomotion, Physical Fitness, Training

Outcome measures

Primary outcome

Effect size of training regarding cardiorespiratory fitness, energy cost of locomotion and daily physical activity level in ambulatory children with Spina Bifida.

Secondary outcome

(1) description of levels of fitness , energy cost of locomotion and level of physical activity (both intensity, amount and type of physical activity); (2) relationship between physical activity, physical fitness and energy cost of locomotion; (3) a description of determinants of physical fitness, daily physical activity and energy cost of locomotion in ambulatory children and adolescents with Spina Bifida.

Study description

Background summary

Many studies have shown the association between levels of physical activity (PA) and physical fitness (PF) and overall mortality and morbidity, not only in adults, but also in children. While healthy children are already at risk for a hypoactive lifestyle in this modern society, this is even more the case in children with chronic disease or disability. In children and adolescents with Spina Bifida (SB), small pilot studies have shown these children to be less

active, less fit and more obese than their healthy peers. Next to increased health risk, these children also seem to be more fatigued during daily activities, which might be related to both low levels of exercise capacity and higher energy expenditure during activities which include ambulation. Earlier studies looking at exercise programs for children with disability or chronic disease have shown increased levels of fitness.

Study objective

Primary objective:To evaluate the effects of a training program on physical fitness, energy cost of locomotion and daily physical activity in ambulatory children and adolescents with Spina Bifida
Secondary objectives: (1) evaluate physical fitness (body composition, muscular strength and cardiorespiratory fitness), daily physical activity and energy cost of locomotion, (2) explore the relationship between physical activity, physical fitness and energy cost of locomotion, (3) determine which factors are associated with physical activity, physical fitness and energy cost of locomotion in ambulatory children and adolescents with Spina Bifida.

Study design

Prospective randomized clinical trial. The first (t=0) measurement will also be used to answer question 1-3.

Intervention

A training program aimed at improving both cardiorespiratory fitness and efficiency of locomotion. The trainingprogram will take place in the environment of the child, e.g. the home, school or nearby sport facility. The type of training will be treadmill training, with intensity, frequency and during individually tailored to the patient's ability.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Time to travel to the exercise lab, time to undergo the tests and time to fill out questionnaires (Fatigue scale, demographics and health related issues at the time of measurement). Participants will perform a maximum VO2peak test and an energy cost of locomotion assessment during a 6 minute walking test. Furthermore they will undergo measurement of height, weight, skin folds, circumferences and muscle strength. The physical activity monitor will be fitted and calibrated during their visit to the lab. Physical activity monitors will be returned either by mail or will be picked up at the home. Participants will be exercising twice a week. Each candidate will receive an individually designed home training program, based on the outcomes of maximum exercise testing. The risks of these

tests and training program are negligible. The benefits for these children are participation in the training program. If the exercise program indeed has been proven to be beneficial, the control group will receive training instructions, to be used under supervision of their physical therapist, after the study has been completed.

Contacts

Public
Universitair Medisch Centrum Utrecht

Postbus 85090
3508 AB Utrecht
Nederland
Scientific
Universitair Medisch Centrum Utrecht

Postbus 85090
3508 AB Utrecht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

At least community ambulatory (according to Hoffer et al. , adapted by Schoenmakers et al.)
Be able to follow instructions regarding testing and training
Parental and child informed consent
Age 6-18 years of age

Exclusion criteria

Insufficient understanding of the Dutch language in both children and parents.
Medical events that will not allow exercise testing and/or training.
Children participating in high level sports and/or more than 3 hours a week.
Severe cognitive impairments (IQ<80)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-01-2009
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	21-10-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL24108.041.08