Improving an active lifestyle and sports participation in adolescents and young adults with meningomyelocele (MMC): Optimalisation and evaluation of an intervention.

Published: 18-01-2007
Last updated: 14-05-2024

The purpose of this study is to improve, implement and evaluate an intervention program to improve physical activity in daily life and sportsparticipation of adolescents and young adults with MMC. The purpose of the intervention "Active...

Ethical review	Approved WMO
Status	Pending
Health condition type	Congenital and hereditary disorders NEC
Study type	Interventional

Summary

ID

NL-OMON30620

Source
ToetsingOnline

Brief title
MMCintervention

Condition

- Congenital and hereditary disorders NEC

Synonym
meningomyelocele, Spina Bifida

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Kinderfonds Adriaanstichting en Johanna Kinderfonds

Intervention

Keyword: Active lifestyle, Fitness, Intervention, Meningomyelocele

Outcome measures

Primary outcome

Body composition:

BMI

Daily activity:

"activity counts" as measured with an Actigraph

Fitness:

Maximum oxygen uptake, measured during a maximal exercise test

Secondary outcome

Body composition

Length, weight, percentage body fat, waistcircumference

Daily activity

MET/h per day, measured with a questionnaire (PASIPD).

Fitness:

Distance covered within 6 minutes.

Study description

Background summary

Previous studies have shown that adolescents and young adults with meningomyelocele (MMC) are considerably hypoactive and have lower physical fitness compared to healthy peers. Moreover, relatively active persons with MMC have higher physical fitness compared to hypoactive persons with MMC, and they have less body fat. A hypoactive lifestyle may have negative effects on the quality of life and may lead to secundary complications as cardiovascular diseases and diabetes mellitus 2.

Study objective

The purpose of this study is to improve, implement and evaluate an intervention program to improve physical activity in daily life and sportsparticipation of adolescents and young adults with MMC. The purpose of the intervention "Active Lifestyle and Sportstimulation" is to guide adolescents and young adults to a more active lifestyle, and therefore a more healthy lifestyle and to improve their fitness.

Study design

The intervention Active Lifestyle and Sportsstimulation consists of 4 parts which are under supervision of a personal coach: moving in daily life, fitness training, individual sportscounseling and sportsactivation. The personal coach and the participant together decide in which parts he/she will participate.
Pre- and posttest consists of measuring body compostition, the level of daily activity and fitness.
Also, the applicability and feasibility of the intervention will be evaluated.
Three months after the posttest, the follow-up measurements, which are similar as the pre-and posttest measurments, will take place to obtain insight in the long term effects of the treatment

Intervention

The intervention Active lifestyle and Sportsstimulation available at the outpatient clinics for Young adults aims at improving the level of daily activity and sporstparticipation for adolescents and young adults with meningomyelocele. The intervention consists of four parts which are under supervision of a personal coach: movement in daily life, fitnesstraining, individual sportscounseling and sportsstimulation. The personal coach and

participant will decide together in which parts and in which amount the participant will participate.

Study burden and risks

The duration of the intervention will be 16 weeks. The intervention consists of 4 counseling sessions with the personal coach. The load of the intervention will depend on the individual program that is made by the personal coach and participant. There will be a weekly fitness session at the Erasmus MC, and several participants can try several sports.
The pre- and posttest measurements will take 1 hour. Before performing a maximal exercise test, it will be checked if participants are allowed to perform the test. During the maximal exercise test, there will be a doctor around, which minimized the risks for performing the test. All other tests do not carry any risks.
Three months after the post-test, follow-up measurements will take place. These measurents are simalar to those during the pre- and posttest.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr Molewaterplein 40
3000 DR Rotterdam
Nederland
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr Molewaterplein 40
3000 DR Rotterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- diagnosis MMC
- age 16 - 25 years
- known in Erasmus MC in outpatient clinic for Young adults

Exclusion criteria

- complete dependence of an electric wheelchair
- disorder other than MMC that contra-indicates physical activity (i.e. lung disorder)
- disorder that contra-indicates a maximal exercise test
- not able to understand the research assignments and therapy instructions

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2006
Enrollment:	16

Type:	Anticipated

Ethics review

Approved WMO Date:	18-01-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL11938.078.06