LEARN2MOVE 16-24: Effectiviteit van een leeftijdsspecifieke interventie ter bevordering van mobiliteit-gerelateerde dagelijkse activiteit en fysieke fitheid van jongeren en jongvolwassenen met spastische cerebrale parese.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24046

Source
NTR

Brief title
LEARN2MOVE 16-24

Health condition

Spastic cerebral palsy

Sponsors and support

Primary sponsor: Erasmus Medical Center, Department of Rehabilitation Medicine
Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

1. The level of daily activity, measured with an ambulant activity monitor. By use of this monitor the following parameters will be calculated:

A. Duration of dynamic activities;

B. Duration of static activities;

C. Number of transitions;

D. Number of perionds of continuous dynamic activities;

E. Distribution of perionds of continuous dynamic activities;

F. Motility (movement intensity).

2. Physicall fitness which is subdiveded into cardiorespiratory (obtained during progressive cycling or armcranking test and 6 minute walking or wheelchair riding test), neuromuscular (obtained with hand held dynamometry) and metabolic fitness (obtained with heigth, waist circumference, weight, BMI and skinfold test).

Secondary outcome

1. Fatigue:

A. Fatigue severity questionnaire (FSS);

B. VAS;

C. Checklist individual strength.

2. Participation:

A. Life habits 3.0, shortened version questionnaire.

3. Quality of life:

A. Short Form 36 questionnaire.

4. Capacity for mobility related activities:

A. Lateral step up test (number of lateral step ups in 15 seconds);

B. The Timed Stairs Test (required time to walk up and down the stairs);

C. Gross motor activities (measured with the GMFM, dimension d & e).

Study description

Background summary

The aim of the research is to evaluate the efficacy and working mechanisms of the "active lifestyle" intervention, which is directed to strategies to prevent low levels of daily activities and poor fitness in adolescents and young adults with cerebral palsy. The intervention consists of different parts with e.g. a physical training program en strategies to achieve a change in lifestyle with respect to the daily activity. This intervention will be evaluated in this longitudinal research by comparing several outcome measures between a group of persons with CP receiving the intervention and a group of persons with CP receiving no intervention (regular at this age). To evaluate the working mechanisms, the focus will be on the relation between mobility related activites, physical fitness and obesity.

In this longitudinal multicenter research an intervention will be evaluated on adolescents with spastic CP. The measurements will take place before, during and direct after finishing the intervention. There will be a follow-up measurement 12 months after the start of the intervention.

The research sample will be randomly divided into two groups. The experimental group will receive the intervention “Active Lifestyle and Sports participation” and the control group will receive no intervention, which is regular at adolescent age. The research assistants which will perform the measurements are blinded for treatment allocation.

It is possible for the participant allocated to the control group, to start the intervention after finishing the research.

Study objective

We hypothesize that by following the intervention the participants will learn a more active lifestyle.

Study design

1. 09-2008 / 09-2009: preparation trial;

2. 09-2009/09-2011: inclusion period;

3. 09-2011/09-2012: data analysis & publication.

Intervention

The intervention “Active Lifestyle and Sports Participation” consists of 3 parts:

1. Personal counseling; this part aims to achieve a behavioral change towards a more active lifestyle by means of 6 individual counseling sessions with a personal coach. This part of the intervention is based on the ‘Stages of Change’ concept of the transtheoretical model. This model distinguishes 5 stages and each stages needs a different approach of the personal coach to stimulate a change in behaviour. Duration; 6 months;

2. Fitness training; this part aims to improve the physical fitness of the participants and consists of group training sessions in the centre and home training sessions (both 1 hour / week). The training is directed to improve the aerobic capacity and the muscle force. Group training sessions are under supervision of a physical therapist. Home training sessions will be monitored by heart frequency registration. The duration of this part of the intervention is 3 months. After this period the possibilities will be explored to continue the training in the periphery;

3. Sports Participation; This part of the intervention consists of 2 to 5 counseling sessions with a sports counsellor where the preferences and possibilities of sports activities are discussed. In this way the sports counsellor can create a tailored sports advice. It is also possible to follow several sport specific workshops. The duration of this part of the intervention is variable with a maximum of 6 months. This part of the intervention is optional.

An individual approach is applied during all parts of the intervention (tailored treatment).

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Eligibility criteria

Inclusion criteria

1. Spastic CP;

2. Adolescents and young adults (16 - 24 years);

3. Gross Motor Function Classification System (GMFCS); level I - IV.

Exclusion criteria

1. Other disorders that may interfere with the measurements;

2. Contra-indication for (maximal) exercise;

3. Not able to understand the purpose of the research due to insufficient knowledge of the dutch language or cognitive or any other disorders;

4. High baseline level regarding physical activity.

Study design

Design

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

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2009
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-04-2009
Application type:	First submission

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
NTR-new	NL1684
NTR-old	NTR1785
Other	MEC ErasmusMC / CCMO : 2009-079 / NL25102.078.09
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A