

Accelerometry as a Measure of Physical Activity and Inactivity in Children with Chronic Disease

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1. To determine the applicability of standard energy expenditure prediction equations for accelerometry in measuring physical activity in children with musculoskeletal and other chronic diseases (see below). 2. To develop disease specific prediction...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital cardiac disorders
Study type	Observational non invasive

Summary

ID

NL-OMON31780

Source

ToetsingOnline

Brief title

Accelerometry in Chronic Illness

Condition

- Congenital cardiac disorders
- Joint disorders
- Neuromuscular disorders

Synonym

chronic illness

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Canadian Institute for Health Research

Intervention

Keyword: accelerometry, energy expenditure, oxygen uptake, physical activity

Outcome measures

Primary outcome

The main study parameter is the agreement between predicted energy expenditure from accelerometry counts compared to directly measured energy expenditure via metabolic cart.

Secondary outcome

We will begin to develop disease specific prediction equations - where necessary - to determine the relationship between accelerometry counts and energy expenditure in these groups.

We will compare 2 different accelerometers (Actical with Actigraph) to determine if one is superior in predicting energy expenditure compared to the other.

Study description

Background summary

This pilot study will provide tools with which to better study the interaction between physical activity and musculoskeletal disease in children. Habitual physical activity may play an important role in the prevention or attenuation of chronic disease. Assessment of physical activity can be used to determine disease specific rehabilitation programs and to measure outcomes in research interventions. Accelerometry, a measure of physical activity, has been shown to be valid and reliable way to characterize physical activity patterns in healthy children but may not be valid in chronic disease. The applicability of

accelerometry must be determined in children with chronic disease.

Study objective

1. To determine the applicability of standard energy expenditure prediction equations for accelerometry in measuring physical activity in children with musculoskeletal and other chronic diseases (see below).
2. To develop disease specific prediction equations - where necessary - to determine the relationship between accelerometry counts and energy expenditure for each of these groups of children.
3. To compare the applicability of unidirectional (vertical) and omni-directional (all directions) accelerometers in predicting energy expenditure.

Study design

This is an observational study in which children will participate in a single exercise testing session at SickKids or UMC. Energy expenditure measured via expired gas using a metabolic cart and accelerometry counts will be determined for each subject while completing two exercise protocols. Exercise protocol: Children will participate in two treadmill walking tasks followed by a jogging task at a self-selected pace. Activities of daily living protocol: Each participant will engage in 7 minutes each of playing video games while seated, a cleaning task (sweeping), two jumping tasks, and a stair-stepping routine. These protocols represent the spectrum of intensity range of activities that a child might engage in during a typical day. Other measures include heart-rate monitoring, self-report physical function and health-related quality of life and assessments of pain using 10cm visual analog scales.

Study burden and risks

Participants will be asked to take part in one exercise testing session that will last approximately 2.5 hours. They will be asked to participate in several exercise tasks, several daily living tasks, and will be asked to fill in 4 questionnaires. The level of discomfort should be minimal as all of these tasks are safe for children to perform. They may experience some muscle soreness or stiffness, but this should not worsen their disease or disability.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Age 8 to 18 years.

Both prepubescent and pubescent children will be enrolled.

- Healthy controls - will include any child without a history of disease or disability who are able to cooperate with the testing procedures.
- Diagnosis of Juvenile Idiopathic Arthritis (JIA) - based on the ILAR criteria (56) OR
- Diagnosis of Severe Hemophilia A or B ($< 1\%$ clotting factor activity) OR
- Diagnosis of Juvenile Dermatomyositis (JDM) - based on the Bohan & Peter criteria OR
- Diagnosis of dystrophinopathy (Beckers, Duchenne*s) or other inherited muscle disease OR
- Diagnosis of Cerebral Palsy (Gross Motor Function Classification system Levels I or II) (57) OR
- Diagnosis of Cystic Fibrosis OR
- Diagnosis of congenital heart disease (CHD) and Fontan procedure or tetralogy of Fallot repair.

Exclusion criteria

Medical status that will not allow exercise testing

Medications that interfere with heart rate response to exercise

Non-ambulation: patients who are unable to ambulate

Insufficient understanding of the Dutch language in both children and parents

See also page 14 of the protocol

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 25-03-2008

Enrollment: 80

Type: Actual

Ethics review

Approved WMO

Date: 04-03-2008

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	NL18035.041.07