The ultimate nutrition study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON31203

Source
ToetsingOnline

Brief title
The ultimate nutrition study

Condition

- Other condition

Synonym
energy balance; body composition

Health condition

geen aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: ZonMW;NEMO en Nederlands Genomics Initiatief

Intervention

Keyword: Body composition, Food intake, Physical activity, Physical fitness

Outcome measures

Primary outcome

Reported energy intake and reported physical activity;

Measured physical activity, physical fitness and body composition

Secondary outcome

none

Study description

Background summary

This study is performed in the context of a public event that aims to acquaint children in the final year of pre-school (basisschool groep 8) with scientific research. Classes participate in a science-teaching program provided by the applicants that ends with a contest in which children write their own research proposal. The two winning classes of the contest will be part of a *real* research project. In this project, they will be researcher, statistician, technician or press officer but also function as subject / volunteer of the study. The schools that participate in the teaching program and contest will be informed in advance that the prize consists of a project that asks for participation of the children.

Study objective

The design of the project is such that the results will be publishable in a scientific journal and will contribute to insight into the relation between food intake and physical activity and physical fitness and body composition. Earlier research in adults showed a significant underreporting of food intake as compared with estimated energy expenditure based on physical activity and body composition. Additionally, there was a significant relation between physical activity and physical fitness and body composition. The more active subjects were fitter and leaner. Here, similar observations will be performed in children to study whether the relations as observed in adults already exist in this age group.

Study design

Cross-sectional observational study

Study burden and risks

The two participating classes will be visited at the onset of the project and the children will be asked to keep a food diary for one week and to carry a small device that registers body movement for one week. Subsequently, the children will come to the NEMO science center for a two-day visit. There: they will be subjected to a short evaluation of their physical condition using a treadmill and (Polar) heart rate monitor at sub-maximal exercise intensity; body composition will be determined by air-displacement plethysmography using a BodPod apparatus (body volume) and by deuterium dilution (total body water); they will evaluate their own food- and activity record with a computer simulation programme.
The time investment requested from the participating children is 2 hours at the onset of the study (including explanations), 30 minutes per day for 7 days (dietary intake and activity monitor), and 2 x 3 hours when the study is ended at the NEMO science center.
There are no risks associated with the participation in the project.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Girls and boys
Age 11-13 year
Informed consent signed by the parents and the child

Exclusion criteria

none

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-04-2007
Enrollment:	60
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	16-04-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL16374.068.07