Accuracy and repeatability of two indirect calorimeters for measuring resting energy expenditure (REE) in adolescents and adults.

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Primary objectives: this study will 1) assess the accuracy of the Cortex MetaLyzer® 3B in adolescents (12-17 yr) for measuring REE, using the Deltatrac® II metabolic monitor as a reference; and 2) assess the accuracy and the within-subject, within-...

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON42914

Source
ToetsingOnline

Brief title
Accuracy of two indirect calorimeters

Condition

- Other condition

Synonym
Not applicable

Health condition

N.v.t.

Research involving

Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Accuracy, Indirect calorimetry, Metabolic monitor, Resting energy expenditure

Outcome measures

Primary outcome

The main study parameters are the VO2 (ml/min), VCO2 (ml/min) and RQ which are measured with alternating use by the indirect calorimeters. These parameters make it possible to calculate REE (MJ/day), which is the primary endpoint.

Secondary outcome

The parameters weight (kg), height (m), and body mass index (BMI, kg/m2) are measured by scale and stadiometer. With these parameters the REE (MJ/day) can be derived using the prediction equations. The predicted REEs are compared with the measured REEs.

Study description

Background summary

The estimation of energy expenditure in an individual is essential in nutritional assessment, to determine energy requirements. In practice, energy requirements are often estimated, by experts, through prediction equations. However, these equations are lacking accuracy on the individual level due to high variation of many covariates, both in adolescents and adults.
Indirect calorimetry is seen as a gold standard for measuring energy expenditure. By using indirect calorimeters, the energy expenditure is determined by measuring oxygen consumption (VO2) and carbon dioxide production (VCO2).

In clinical practice, indirect calorimetry is the most preferable method to use. Unfortunately, traditional indirect calorimeters are cumbersome, require skilled operators, and are costly to maintain. Therefore, it is desirable to test existing, portable indirect calorimeters on accuracy.

Study objective

Primary objectives: this study will 1) assess the accuracy of the Cortex MetaLyzer® 3B in adolescents (12-17 yr) for measuring REE, using the Deltatrac® II metabolic monitor as a reference; and 2) assess the accuracy and the within-subject, within-day repeatability of the MedGem® in adults (18-65 yr) for measuring REE, using the Deltatrac® II metabolic monitor as a reference. Secondary objective: evaluate frequently used prediction equations by comparing measured REE*s with predicted REE*s.

Study design

The study will have a crossover design. REE (in MJ/day) measurements will be performed during one session, with alternating use of either the Cortex MetaLyzer® 3B (facemask) or the portable MedGem® (mouthpiece) with the Deltatrac® II metabolic monitor (ventilated-hood) as a reference method. Furthermore, body composition measurements by bio-impedance spectroscopy (BIS) and body weight and height measurements will be conducted.

Intervention

Not applicable

Study burden and risks

All measurements, with indirect calorimeters, bio-impedance spectroscopy and anthropometry device, are safe and non-invasive. This study is in no way burdensome for the participants. The benefits of using indirect calorimetry is that energy expenditure of an individual can be accurately determined. This study will test the accuracy of indirect calorimeters in apparently healthy individuals.
This study is regarded as group-related, since it has been designed in response to an inquiry of the Wilhelmina Children's Hospital in Utrecht. Without contribution of apparently healthy adolescents with approval of their parents/guardians, the study cannot be conducted.

Contacts

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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

- apparently healthy (self-indicated);
- adolescents 12-17 years of age;
- adults 18-65 years of age.

Exclusion criteria

- adults with a BMI <18.5 or >30;
- pregnancy;
- having self-indicated claustrophobia or respiratory problems e.g. due to a common cold;
- having a pacemaker;
- participating in other scientific research.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	60
Type:	Anticipated

Ethics review

Not approved

Date:	15-12-2016
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL60001.081.16