Use of the Tanita TBF-300M body composition analyser in children with cystic fibrosis and healthy controls: a validation study using air displacement plethysmography

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To assess whether the Tanita body composition analyser - a simple non-invasive device to estimate body composition - can be used to estimate body fat% in children and adolescents with cystic fibrosis in cross-sectional and longitudinal studies.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON30228

Source
ToetsingOnline

Brief title
The Tanita-BodPod body composition study

Condition

- Other condition

Synonym
nvt

Health condition

gezonde proefpersonen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: air displacement plethysmography, bio impedance analyzer, body composition, cystic fibrosis

Outcome measures

Primary outcome

fat free mass and fat mass

Secondary outcome

not applicable

Study description

Background summary

Cystic fibrosis (CF) is an inherited chronic illness characterised by exocrine pancreatic failure and chronic respiratory infections. Malnutrition is a common but largely preventable complication in children and adolescents with CF. Nutritional care is considered an essential component of cystic fibrosis (CF) management. Anthropometric measurements are routinely performed to assess growth and nutritional status.

In addition to body weight and height measurements, body fat is estimated in most CF patients, often from the measurement of skinfold thickness which can be performed at low cost and is painless. However, its reproducibility is dependent on the technician and validity depends on the amount of body fat. Another non-invasive technique for the assessment of body composition that is rapidly gaining popularity in the clinical setting is the Tanita leg-to-leg bioimpedance analyser (BIA). The Tanita is portable, easy to use for patients and technicians, and relatively inexpensive. The built-in BIA provides a measurement of resistance (in Ohm) and estimates of total body water and body fat. In healthy non-obese children, the Tanita proved to be reproducible and

valid when compared to DEXA (1). Although Tanita readings are useful in adult CF patients (2) no validation studies with Tanita in CF patients have yet be published.

Our plan is to validate the Tanita-300M for children aged 7-18 years . Hydrostatic weighing would be the gold standard for the measurement of body volume, body density and - as a derivative - body fat, but this is not feasible in patients who have difficulties to breathe. A novel gold standard is air displacement plethysmography, which can be measured non-invasively using the Bodpod® device. In a recent study in 23 healthy children from Wageningen, the Bodpod® had excellent accuracy and repeatability compared to hydrostatic weighing (3). Thus, air displacement plethysmography will be used a reference method.

To check whether air displacement plethysmography is a valid reference method in CF children, we will also perform the two methods in healthy controls.

Study objective

To assess whether the Tanita body composition analyser - a simple non-invasive device to estimate body composition - can be used to estimate body fat% in children and adolescents with cystic fibrosis in cross-sectional and longitudinal studies.

Study design

All children will be measured with the Tanita and the reference method, Bodpod®, at two time points with 4 months in between:

month controls (WU) CF (UMCU)

Nov 2007 measurement 1
Jan 2007 measurement 1
March 2007 measurement 2
May 2007 measurement 2

The data collected during the first and second measurements (1 and 2) will be used to compare body fat% measured by Bodpod® and Tanita using the Bland-Altman analysis. This will be done for control children and CF patients separately.

The repeated measurements after 4 months will be used to assess changes (2 - 1) in body fat% using the two methods.

The study will be observational; no intervention other than standard care will be provided. Changes in food intake or physical exercise are allowed because

they do not interfere with our study.

Study burden and risks

The bioimpedance measurement with Tanita is safe, noninvasive, rapid (ca 30 s), and familiar because it resembles standing on a normal bathroom scale.
The Bodpod® measurement is safe, but not suitable for claustrophobic persons.
All children will be made familiar and at ease with the measurements; no pressure will be put on them to take part.
All participants will receive a report with their body weight, height, and body fat%. The healthy controls - who voluntarily take part - will receive a small fee or gift.

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

apparent healthy children, age 7-18

Exclusion criteria

18

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2006
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

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	NL14764.081.06