ISRCTN09100243 https://doi.org/10.1186/ISRCTN09100243

Obesity in children and adolescents with a high risk of insulin resistance

Submission date	Recruitment status	[X] Prospectively registered
12/12/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/01/2008	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
15/09/2008	Nutritional, Metabolic, Endocrine	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Michael Ranke

Contact details
University Children's Hospital
Hoppe-Seyler-Strasse 1
Tuebingen
Germany
72076

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Investigation of overweight/adipose children and adolescents who face a high risk of insulin resistance: dietary intervention, exercise treatment and pre- and post-treatment status in the DISKUS study

Acronym

DISKUS study

Study objectives
The number of overweight children has risen staggeringly in Germany. Overweightness is associated with the metabolic syndrome and, by extension, with a high risk of cardiovascular morbidity and mortality. Up to now, attempts to treat children and adolescents have basically been limited to interventions targeting lifestyle. They have often not produced lasting effects, neither is it clear why these endeavours are shortlived. Our approach in attempting to clarify this issue is to undertake a comprehensive investigation of children and adolescents who face a high risk of the metabolic syndrome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethics Committee of the University of Tuebingen on the 13th June 2007 (ref: 130/2007BO1).

Study design
Our study is a prospective, controlled, open, non-randomised investigation.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Childhood obesity, metabolic syndrome

Interventions
Schematic diagram of the trial design (intervention group):
Preliminary examination: Presentation and examination at the Hospital for Children and Adolescent Medicine (one half-day visit) and at the Department of Sports Medicine (one half-day visit), including counselling by a sports medicine clinician. Sub-group: Additional investigations in 30 randomly-chosen patients: Mental Rotations Test (MRT), eye-tracking.
Months 1 - 6: Two nutritional counselling sessions focusing on the subjects of food and beverage choices, implementation in daily life. Physical activity and exercise at home (involving family, friends, recreational centre/sports club) as recommended by the sports medicine clinician.
Month 6: First interim examination (same as first visit). Visit additionally includes the analysis of a four-day eating protocol and the physical activity log book, followed by counselling. Sub-group (n = 30): Additional investigations comprise MRT and eye-tracking.
Months 7 - 12: Nutritional counselling session and/or further sports medicine instruction if required for exercise at home (involving family, friends, recreational centre/sports club) as recommended by the sports medicine clinician.
Month 12: Second interim examination (same as first visit). Visit additionally includes the analysis of a four-day eating protocol and the physical activity log book, followed by counselling.
Months 12 - 24: Observational phase: the intervention is implemented independently by the volunteer.
Month 24: Final examination (same as first visit). Visit additionally includes the analysis of a four-day eating protocol and the physical activity log book, followed by counselling.

Schematic diagram of the trial design (control group):
Preliminary examination: Presentation and examination at the Hospital for Children and Adolescent Medicine (one half-day visit).
Months 1 - 6: One nutritional counselling session focusing on the subjects of food and beverage choices, implementation in daily life.
Month 6: First interim examination (same as first visit). Visit additionally includes the analysis of a four-day eating protocol.
Months 7 - 12: Nutritional counselling session if required.
Month 12: Second interim examination (same as first visit). Visit additionally includes the analysis of a four-day eating protocol.
Months 12 - 24: Observational phase: the intervention is implemented independently by the volunteer.
Month 24: Final examination (same as first visit). Visit additionally includes the analysis of a four-day eating protocol.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Significant yearly changes in the BMI (Standard Deviation Score [SDS])
2. Significant yearly changes in the level of fasting insulin (HOmeostasis Model Assessment of Insulin Resistance [HOMA-IR])

Outcomes measured at baseline and months 6, 12 and 24.

Key secondary outcome(s))
1. Improvements in physical fitness:
1.1. Ventilatory threshold
1.2. Period of total load
1.3. Subjective fatigue
1.4. Maximum heart rate
1.5. Watt-max test
1.6. Oxygen uptake
2. Lowering of the systolic/diastolic blood pressure to below the 95th centile
3. Improvements in the levels of High Density Lipoprotein (HDL) cholesterol, lowering of levels triglyceride levels
4. Reduction or reversal of pathological status of thickness and proportion of abdominal fat /skinfold thickness
5. Boost in general vigour
6. Improvement of well-being and mood, enhancement of health-related quality of life

Outcomes measured at baseline and months 6, 12 and 24.

Completion date
01/08/2010

Eligibility

Key inclusion criteria
1. Overweight (Body Mass Index [BMI] greater than 90th centile) or obese (BMI greater than 97th centile)
2. Children and adolescents between the ages of 6 and 18 years
3. One or more of the following criterias:
3.1. Extreme obesity (BMI greater than 99.5 centile of age- and sex-matched references)
3.2. First-degree relative with type 2 diabetes/diabetes during pregnancy or two grandparents with type 2 diabetes
3.3. Neonatal size either small or large for gestational age (birth weight or birth length less than 5th/greater than 95th centile)
3.4. Acanthosis nigricans
3.5. Polycystic ovary syndrome
3.6. Children and adolescents with established glucose tolerance impairment, abnormal levels of fasting glucose, type 2 diabetes

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
18 years

Sex
All

Key exclusion criteria
1. Type 1 diabetes
2. Eating disorder
3. Pregnancy
4. Neoplasm or severe systemic disease
5. Cardiovascular disease
6. Mental retardation
7. Mental health problem

Date of first enrolment
01/02/2008

Date of final enrolment
01/08/2010

Locations

Countries of recruitment
Germany

Study participating centre
University Children's Hospital
Tuebingen
Germany
72076

Sponsor information

Organisation
University Children's Hospital of Tuebingen (Germany) - Section of Pediatric Endocrinology

ROR
https://ror.org/03esvmb28

Funder(s)

Funder type
Government

Funder Name
German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany) - an application for a Research Grant has been submitted

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration