## Trial Description

### Title

**Identification and Characterization of Youth with Extreme Obesity, Subproject 1**

### Trial Acronym

**YES**

### URL of the trial

**https://www.uniklinik-ulm.de/kinder-und-jugendmedizin/sektionen-ambulanzen-und-arbeitsbereiche/sektion-paediatrische-endokrinologie-und-diabetologie/klinische-studien-und-experimentelle-forschung/klinische-studien.html**

### Brief Summary in Lay Language

**While obese and extremely obese youth are at increased risk of health complications, especially the extremely obese group rarely seek medical care. One of the underlying reasons might be the lack of adequate treatment options. This study is a subproject of the "Medical and psychosocial implications of adolescent extreme obesity – acceptance and effects of structured care study", short: "Youth with Extreme obesity Study (YES)", which aims at improving the medical care and social support structures for youth with obesity and extreme obesity in Germany. In this subproject, information on the causes and consequences of extreme obesity will be gathered via questionnaires and medical examinations.**
**Obese youth and young adults (BMI ≥ 30kg/m2) between the ages of 14 and 24.9 years (initially 21 years) are eligible to participate. Participants will be asked to complete a series of questionnaires on their general health, psychosocial situation and wellbeing in 2-3 sessions. They will be offered a thorough medical examination comprising a general check-up, a fasting blood draw and oral glucose tolerance test, a focused orthopaedic examination, a sleep apnea screening, and an ultrasound of the liver. The aim of the study is to elicit the acceptance of diagnostic and therapeutic procedures, and to assess the frequency of co-morbidities in obese and extremely obese youth. This knowledge will optimize medical treatment and support options. Interested participants will be invited to participate in further steps of YES, which entail medical care and psycho-social support.**
**In February 2013 an amendment was added to the study to include patients up till 24.9 years. In addition, the psychosocial questionnaires were shortened to increase the patients willingness to answer them.**

### Brief Summary in Scientific Language

**While obese youth are at high risk for co-morbidities, especially the extremely obese individuals rarely seek medical care. The underlying reasons are poorly understood, but patient inherent factors and the lack of adequate treatment options may play a role. In this multicenter study, we aim to recruit adolescents from various medical and non-medical settings and examine their acceptance of**

**diagnostic and subsequent treatment procedures. We will compare the prevalence rates and severity of co-morbidities between adolescents with extreme obesity and those with less severe obesity. This project is part of the "Medical and psychosocial implications of adolescent extreme obesity - acceptance and effects of structured care study", short: "Youth with extreme obesity Study (YES)", which also comprises a randomized controlled trial to investigate a novel intervention targeted at improving quality of life and social functioning of extremely obese adolescents, a structured prospective evaluation of adolescent bariatric surgery, economic assessments of the financial burden of extreme adolescent obesity on the healthcare system, and a long-term prospective observation study.**

**Based on the current state of knowledge, we have formulated the following hypotheses in regards to baseline characteristics:**
**1. The prevalence of somatic, psychiatric and psycho-social co-morbidities is higher, and health related quality of life is lower in extremely obese youth compared to the control group.**
**2. The prevalence of somatic co-morbidities is equal in treatment-seeking and non treatment-seeking youth.**
**3. The prevalence of psychiatric co-morbidities is higher and health related quality of life is lower in treatment-seeking compared to non treatment-seeking youth.**
**4. The acceptance of diagnostic and therapeutic procedures is lower in extremely obese youth compared to the control group.**
**5. The acceptance of diagnostic and therapeutic procedures is lower in non treatment-seeking- compared to treatment-seeking youth.**
**6. Socio-economic status, intelligence and educational status are predictors of treatment seeking behaviour and of the acceptance of diagnostic and therapeutic procedures.**

**The five participating university centers are distributed across 4 geographic regions in the North (Berlin), in the West (Essen/Datteln), in the East (Leipzig) and in the South (Ulm) of Germany, and will therefore render data that are representative of Germany as a whole. We will recruit a total of 600 adolescents age 14 to 24.9 years (initially 21 years) with extreme obesity (BMI ≥ 35 kg/m2) and 600 adolescents with obesity (BMI 30-34.9 kg/m2) over a 24 months period. Baseline assessments include an array of standardized questionnaires and validated instruments to assess health, psycho-social situation, psychiatric co-morbidities and health related quality of life, as well as a physical examination, laboratory tests, liver ultrasound, and screenings for orthopedic co-morbidities and sleep apnea. Subjects who participate in the baseline examination will be invited to participate in the subsequent components of YES.**

**The project will reveal comorbidity rates and psycho-social situation, and demonstrate the acceptance and outcomes of a structured healthcare program for adolescents with extreme obesity. The planned subsequent longitudinal study will provide unique information on the medical and psychosocial development of adolescents with extreme obesity in Germany.**

## Organizational Data

- DRKS-ID: **DRKS00004172**
- Date of Registration in DRKS: **2012/06/21**
- Date of Registration in Partner Registry or other Primary Registry: **2012/06/19**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**

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- (leading) Ethics Committee Nr.: **89/12 , Ethik-Kommission der Universität Ulm**

## Secondary IDs

- Universal Trial Number (UTN): **U1111-1131-4384**
- Primary Registry-ID: **NCT01625325 (ClinicalTrials.gov)**
- Sponsor-ID: **01GI1120A (BMBF Förderkennzeichen)**
- Other Secondary-ID: **DRKS00004195 (Teilprojekt 2 / Subproject 2)**
- Other Secondary-ID: **DRKS00004196 (Teilprojekt 3 / Subproject 3)**
- Other Secondary-ID: **DRKS00004197 (Teilprojekt 4 / Subproject 4)**
- Other Secondary-ID: **DRKS00004198 (longitudinale Beobachtungsstudie / longitudinal observation study)**

## Health condition or Problem studied

- ICD10: **E66 - Obesity**

## Interventions/Observational Groups

- Arm 1: **obese youth (BMI 30-34,9kg/m2):**

  **Standardized questionnaires on health, quality of life, psychosocial status and psychiatric conditions, physical examination, fasting blood draw, oral glucose tolerance test, liver ultrasound, sleep apnea screening, orthopedic examination.**
- Arm 2: **extremely obese youth (BMI ≥35kg/m2):**

  **Standardized questionnaires on health, quality of life, psychosocial status and psychiatric conditions, physical examination, fasting blood draw, oral glucose tolerance test, liver ultrasound, sleep apnea screening, orthopedic examination.**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Diagnostic**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

### Primary Outcome

**Percentage of subjects that participate in the fasting blood draw. Subjects will be recommended a diagnostic blood draw. The percentage of subjects that participate in this blood draw will be calculated.**

### Secondary Outcome

**1. Percentage of subjects that undergo the other recommended diagnostic procedures.**
**2. Predictors of the acceptance of the diagnostic procedures**
**3. Prevalences of somatic co-morbidities (via standardized physical examination, laboratory and apparative tests, and standardized patient questionnaires at baseline)**
**4. Prevalences of psychiatric co-morbidities (via validated patient questionnaires at baseline - psychiatric screening: Depression: BDI 2, social fear: SPAIK (<18y) / SASKO (≥18y),**
**ADHD: <18y: DISYPS-II SBB-ADHS +DISYPS-II FBB-ADHS (for parents and teachers)/ ≥18y: ADHS-SB Hase (changed in a study amendment in February 2013))**
**5. Percentage of subjects that initiate a standardized low key intervention as described in subproject two.**
**6. Percentage of subjects that accept**
**treatment of somatic co-morbidities (Appropriate medical treatment of the diagnosed somatic co-morbidities will be offered to all subjects. The percentage of subjects who initiate such therapy will be calculated at baseline.)**
**7. Percentage of subjects that accept treatment of psychiatric co-morbidities (Appropriate psychiatric treatment of the diagnosed somatic co-morbidities will be offered to all subjects. The percentage of subjects who initiate such therapy will be calculated at baseline.)**
**8. Predictors of acceptance of treatment of co-morbidities**
**9. Health related quality of life (EQ5Dand disabkids at baseline; changed in a study amendment in February 2013)**
**10. Socio-economic status (standardized questionnaires at baseline - modified**

## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- University Medical Center **Sektion pädiatrische Endokrinologie und Diabetologie, Universitätsklinik für Kinder- und Jugendmedizin, Ulm**
- University Medical Center **Vestische Kinder- und Jugendklinik, Witten**
- University Medical Center **Charité, Ambulantes Adipositas Zentrum Interdisziplinäres SPZ der Kinderklinik, Berlin**
- University Medical Center **Klinik und Poliklinik für Kinder- und Jugendmedizin am Universitätsklinikum, Leipzig**
- University Medical Center **Klinik für Psychiatrie, Psychosomatik und Psychotherapie des Kindes- und Jugendalters LVR-Klinikum, Essen**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/07/09**
- Target Sample Size: **1200**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **14 Years**
- Maximum Age: **24 Years**

### Additional Inclusion Criteria

**BMI ≥ 30.0 kg/m2, adequate German language skills**

### Exclusion criteria

**none**

## Addresses

- **Primary Sponsor**

  **Sektion Pädiatrische Endokrinologie und Diabetologie, Klinik für Kinder- und Jugendmedizin, Universität Ulm**

**Primary Sponsor**

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## Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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## Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2014/12/22**

## Trial Publications, Results and other documents

- Paper **Publication with the title "Do adolescents with extreme obesity differ according to previous treatment seeking behavior? The Youth with Extreme obesity Study (YES) cohort"**

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**** This entry means that data is not displayed due to insufficient data privacy clearing.*