

PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Structured psychoeducation for unemployed adolescents with extreme obesity in a multicenter observational study focusing on feasibility (STEREOplus), Sub-project 2A

Trial Acronym

STEREOplus

URL of the trial

<http://www.kompetenznetz-adipositas.de/menue/kompetenznetz/konsortien/jugendliche-mit-extremer->

Brief Summary in Lay Language

Obesity occurs more frequently in subjects of a lower socio-economic status and is associated with a lower income and unemployment. On the other hand, there is limited access of individuals with low socioeconomic status to conventional obesity treatments and bariatric surgery.

In STEREOplus we will ascertain unemployed adolescents with obesity and extreme obesity at five job centers in the Ruhr area. Unemployed obese youths and young adults (BMI \geq 30kg/m²) between the ages of 14 and 24.9 years are eligible to participate. Participants will be asked to complete a series of questionnaires on their general health, psychosocial situation and wellbeing, and will be offered a thorough medical evaluation. Individuals who complete the baseline evaluations will be invited to participate in six group sessions of conventional obesity treatment over a three months period. After six months, participants will complete further questionnaires to evaluate the effects of the interventions on quality of life and psycho-social functioning. Weight status (BMI) will also be measured. Adolescents who attended at least five sessions and are interested in bariatric surgery will have access to a structured information and preparation program for bariatric surgery.

The overall objective of STEREOplus is to generate data on the feasibility of the planned implementation of a treatment targeted to a high risk group with a low socio-economic back-ground in order to reduce treatment barriers.

Brief Summary in Scientific Language

Obesity occurs more frequently in subjects of a lower socio-economic status and is associated with a lower income and unemployment. Besides the obesity-related impairments in daily life, stigmatisation additionally aggravates the difficulties of vocational integration by multiple disadvantages in the process of application for employment, job interviews and performance evaluation. On the other hand, there is limited access of individuals with low socioeconomic status to conventional obesity treatments and bariatric surgery.

In this multicenter observational study, we aim to assess the acceptance of a manual based low key group intervention targeted at unemployed adolescents (BMI \geq 30 kg/m²; 14-24 years old) recruited on the premises of five local job centers in the Ruhr area. The study is part of the "Medical and psychosocial implications of adolescent extreme obesity - acceptance and effects of structured care", short: "Youth with extreme obesity Study (YES), which also comprises the recruitment and characterization of obese (BMI 30-34.9kg/m²) and extremely obese (BMI \geq 35kg/m²) youth from different healthcare- and non healthcare settings, 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. The participating job centers are located in five cities in the West (Ruhr-Area). We will screen 300 unemployed adolescents aged 14 to 24.9 years with obesity and extreme obesity (BMI \geq 30kg/m²) over a 24 month period. A total of 80 subjects will be enrolled. 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 an in-depth medical evaluation. Individuals who complete the baseline evaluations will be invited to participate in six group sessions over a three month period. Adolescents who attended at least five sessions and are interested in bariatric surgery will have access to a structured information and preparation program for bariatric surgery. The adherence and effects of the interventions on BMI, health related quality of life and psycho-social functioning will be assessed via questionnaires after six months. All statistical analyses will be exploratory/descriptive. The project will reveal the feasibility of the implementation of the described intervention approach focusing on reducing treatment barriers for unemployed adolescents with obesity.

Organizational Data

- DRKS-ID: **DRKS00009437**
- Date of Registration in DRKS: **2015/12/08**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **12-5108-BO , Ethik-Kommission der Medizinischen Fakultät der Universität Duisburg-Essen**

Secondary IDs

Health condition or Problem studied

- ICD10: **E66 - Obesity**



Interventions/Observational Groups

- Arm 1: **Behavioral standardized manual-based multidisciplinary routine care (lifestyle intervention), six sessions offered over the course of three to six months with a focus on weight loss. The topics 1) causes, consequences and treatment options of obesity, 2) nutrition, 3) eating behaviors and problem solving strategies, 4) self esteem and emotional eating, 5) exercise, and 6) use of media will be covered.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Single arm study**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*

Primary Outcome

- **Acceptance and adherence (participation rate in the intervention)**
- **Changes in participation rate in the first and second labor market at 6 month follow-up**
- **Changes in BMI at 6 month follow-up**

Secondary Outcome

Changes between baseline and 6 months Follow-up examination in:

- **Quality of life (DISABKIDS questionnaire)**
- **Depression score (Beck Depression Inventory-II)**
- **Self-esteem (Rosenberg scale)**
- **Perceived stress (PSQ Fliege scale)**
- **Somatic and psychiatric disorders**
- **Self-reported physician and therapist contacts**
- **Self-reported time spent outside the home**

Countries of recruitment



- **DE Germany**

Locations of Recruitment

- University Medical Center **Department of Child and Adolescent Psychiatry, LVR Klinikum, Essen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/05/28**
- Target Sample Size: **80**
- 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 \geq 30 kg/m², written informed consent, sufficient knowledge of the German language to participate in the intervention, participation in subproject 1

Exclusion criteria

any psychiatric disorder that requires inpatient treatment (e.g. psychotic disorder, severe depression with suicidal behaviour), IQ < 70

Addresses

- **Primary Sponsor**

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■ **Contact for Scientific Queries**

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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.)**

Bundesministerium für Bildung und Forschung Dienstsitz Bonn

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2017/12/04**

Trial Publications, Results and other documents

* This entry means the parameter is not applicable or has not been set.

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