Trial Description

Title

Feasibility and efficacy of a weight maintenance treatment approach for adolescent obesity via telephone counseling following an obesity treatment program: a randomized controlled trial

Trial Acronym

TeAM (Telephone counselling as an adiposity management program)

URL of the trial

http://www.team.ifb-ag-praevention.de/index.html

Brief Summary in Lay Language

The TeAM (Telephone based adiposity management) program address adolescents (14-18 years) who completed an inpatient obesity therapy. Adolescents will be recruited directly via rehabilitation hospitals, and will then be randomized to a study and a control group. Control group: No intervention, medical care as usual. The intervention consists of a six month telephone counseling through trained prevention managers in order to maintain BMI-SDS-reduction achieved during the inpatient obesity therapy. The telephone interviews are based on the systemic approach. The counseling interviews address the topics mental hygiene, physical activity, sedentary behavior, diet and eating behavior. Prior to the intervention, participating adolescents will be asked to provide information on socio-demography, psychosocial status, daily physical activity and leisure time habits as well as on eating behavior.

Brief Summary in Scientific Language

Maintenance approaches in adolescent obesity are scarce today. To our knowledge, no obesity intervention study for children and adolescents has examined the impact of telephone counseling as an aftercare weight maintenance approach. Thus, the present study aims to evaluate a) the feasibility and b) the efficacy of a six month aftercare weight maintenance treatment (maintaining BMI-SDS, i.e. standard deviation score of body mass index) following reconvalescent care for adolescent obesity based on telephone counseling, with a follow up period of two years.
Adolescents (14-18 years) will be recruited directly via rehabilitation hospitals, and will then be randomized to an intervention and a control group (RCT). The intervention consists of a telephone counseling through trained prevention managers in order to maintain BMI-SDS-reduction achieved during the inpatient obesity therapy.
The telephone interviews are based on the systemic approach according to the solution focused counseling after De Shazer. The counseling interviews address the topics mental hygiene, physical activity, sedentary behavior, diet and eating behavior. The feasibility study is performed with two distinct modes of intervention, i.e. there are two intervention groups and one control group.
Feasibility study intervention groups: One intervention group receives telephone counseling and tailored SMS messages, as integrated everyday life technology in

adolescence. The other intervention group receives telephone counseling, tailored SMS messages and has in addition access to a password-protected web-forum for interaction with other participants. Control group: No intervention, medical care as usual.
The mode of intervention superior over the other will be applied in the efficacy study.
Efficacy study: At the beginning and the end of the intervention, as well as 12 and 24 months after randomization (follow up), anthropometric measurements will be performed in all participants by a pediatrician or general practitioner. These data are transferred into a local database for standardized evaluation and analyses.

Organizational Data

- DRKS-ID: **DRKS00004583**
- Date of Registration in DRKS: **2012/11/30**
- 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.: **AZ 295-12-24092012 , Ethikkommission an der Medizinischen Fakultät der Universität Leipzig**

Secondary IDs

Health condition or Problem studied

- ICD10: **E66.9 - Obesity, unspecified**

Interventions/Observational Groups

- Arm 1: **Intervention group in the efficacy study (6 months) receives telephone counseling (systemic approach according to the solution-focused brief therapy after DeShazer) and tailored SMS messages, as integrated everyday life technology in adolescence. The additional access to a password-protected web-forum for interaction with other participants will be provided, according to the results of the feasibility study (4 months).**

- Arm 2: **Control group: No intervention, medical care as usual.**

Characteristics

- Study Type: **Interventional**

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- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Control group receives no treatment**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The primary outcome is BMI-SDS. Study visits, performed by trained medical staff, include one baseline visit (T0), after written agreement into participation and prior to randomization, and one closing visit after the end of intervention (T1) and two follow up visits (12 and 24 months after randomization (T2+T3)) for both groups (i.e. intervention and control group) to determine baseline and endpoint data.

Secondary Outcome

Both groups are asked to complete questionnaires (at T0, T1, T2 and T3) in order to obtain data on socio-demography, psychosocial status (KIDSCREEN, self image scale), daily physical activity, leisure time habits (MoMo Questionnaire), and eating behavior (DEBQ-K, FFQ) as well as on usage of health services (EQ-5D).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Fachklinik Satteldüne, Amrum**
- Medical Center **Rehaklinik am Kyffhäuser, Bad Frankenhausen**
- Medical Center **Gesundheitspark Bad Gottleuba, Klinik für Kinder und Jugendliche, Bad Gottleuba**
- Medical Center **Charlottenhall, Bad Salzungen**
- Medical Center **Edelsteinklinik, Bruchweiler**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/12/19**
- Target Sample Size: **150**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **14 Years**
- Maximum Age: **18 Years**

Additional Inclusion Criteria

adolescents aged 14-18 years, completion of a structured inpatient obesity therapy program (reconvalescent care), Informed consent of parents or guardians and of adolescents themselves into participation

Exclusion criteria

current involvement in weight loss treatment, psychiatric conditions interfering with participation (e.g. eating disorder, psychosis), medication interfering with participation or weight maintenance, underlying chronic disease interfering with weight maintenance

Addresses

- **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): **2015/04/30**

Trial Publications, Results and other documents

- Paper **Markert J, Herget S, Falkenberg C, Blüher S. Case management via telephone counselling and SMS for weight maintenance in adolescent obesity: study concept of the TeAM program. BMC Obesity 2014;1:8.**
- Paper **[---]***

** 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.*