

Trial Description

Title

"Five A's counseling in weight management of obese patients in primary care: A cluster-randomized controlled trial (INTERACT)."

Trial Acronym

INTERACT-study

URL of the trial

http://isap.uniklinikum-leipzig.de/isap.site,postext,ag-public-health,a_id,1653.html

Brief Summary in Lay Language

The primary health care setting is considered as one major starting point in successful weight management. General Practitioners (GPs) are among the first to be contacted when secondary diseases and comorbidities arise. In addition, it has been shown that GPs advice to lose weight is a strong motivator for patients to engage in weight management strategies. However, research indicates insufficient quality of weight counseling in primary care due to negative attitudes towards obese patients and a lack of self-efficacy in weight counseling.

In this project, the efficiency of an internet based learning program for providers aiming at the improvement of obesity management will be examined in a sample of GPs. The internet based learning program was developed based on the 5A's guidance for obesity management by the Canadian Obesity Network. For the present study the 5A's guidance for obesity management has been worked up as online tutorial for German GPs. It is planned to implement the online tutorial in co-operating primary health care practices and evaluate its effectiveness by assessing patient's and doctor's perspective on characteristics of weight counseling.

For the present study patients with obesity will be recruited in cooperation with GP practices. Thus, the participating GP practices will be randomly allocated to an intervention group (GPs with access to the 5A online tutorial) and a control group (GPs without access to the 5A online tutorial).

Patients of both groups will fill out questionnaires regarding doctor-patient-interaction, quality of life, the course of weight development, self-stigma and readiness to engage in weight management at three different assessment points (immediately after recruitment, after 6 months, after 12 months).

GPs will fill out questionnaires regarding their counseling behavior, stigma concerning obesity, knowledge about obesity as a chronic condition and satisfaction with that knowledge at two different assessment points (immediately after recruitment and before access to the online tutorial, after 12 months).

Changes over time of outcome measures will be compared between intervention group and control group.

Brief Summary in Scientific Language

This project aims to implement and evaluate the internet based learning program "5A Adipositas Management" (The 5A's of obesity management) to improve



weight counseling within the German primary health care setting.

The 5A's of obesity management specifically focus at health care providers and were developed by the Canadian Obesity Network analog to the 5A Model of smoking cessation. The Five A's of obesity management cover recommendations on how to discuss weight with the patient ("ASK"), assess obesity related risks and causes of weight gain ("ASSESS"), advise on treatment options ("ADVISE"), agree on weight loss expectations and treatment plan ("AGREE") and assist the patient in the ongoing process of losing weight ("ASSIST"). For the present study the 5A's guidance for obesity management has been implemented as online tutorial for German GPs.

The study design is a cluster-randomized controlled trial, in which approximately 20 recruited general practitioners (GP) will be randomized to an intervention group (IG: GPs with access to the 5A online tutorial) and a control group (CG: GPs without access to the 5A online tutorial). The study furthermore aims at including approximately 134 study patients in the study sample in cooperation with these GP practices. Patients will fill out questionnaires regarding doctor-patient-interaction, quality of life, the course of weight development, self-stigma and readiness to engage in weight management at three different assessment points (immediately after recruitment, after 6 months, after 12 months). GPs will fill out questionnaires regarding their counseling behavior, stigma concerning obesity, knowledge and satisfaction with that knowledge about obesity as a chronic condition at two different assessment points (immediately after recruitment and before access to the online tutorial, after 12 months).

Changes over time of outcome measures will be compared between IG and CK.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00009241**
- Date of Registration in DRKS: **2016/02/03**
- 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.: **248-15-13072015 , Ethikkommission an der Medizinischen Fakultät der Universität Leipzig**

Secondary IDs



Health condition or Problem studied

- ICD10: **E66 - Obesity**

Interventions/Observational Groups

- Arm 1: **Treatment as usual in primary care plus access of GPs to an internet based learning program on obesity management (“5A Adiposity Management”).**
The Five A online tutorial comprises five modules (“Ask”, “Assess”, “Advise”, “Agree”, “Assist”) and a quiz (learning check) at the end and takes approximately 25 minutes to complete.
The online tutorial covers recommendations on how to discuss weight with the patient (“Ask”), assess obesity related risks and comorbidities (“Assess”), advise on treatment options (“Advise”), agree on weight loss expectations and treatment plan together with the patient (“Agree”) and assist the patient in the ongoing process of losing weight or maintaining weight loss (“Assist”).
- Arm 2: **Waiting list: Treatment as usual in primary care, GPs get access to the 5A online tutorial after the trial**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, data analyst**
- Control: **Active control (effective treatment of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Change in doctor-patient-interaction, assessment via questionnaire Patient Assessment of Chronic Illness Care (PACIC) at start of study (baseline), after 6 months (follow-up 1) and after 12 months (follow-up 2)

Secondary Outcome

Patients: Weight-management (BMI), quality of life (EQ-5D), stages of change of patients to engage in weight management strategies (Readiness Ruler, Stages of Change), self-stigma (WBIS), depression (PHQ9); Assessment at 3 points in time



(start of study, after 6 months and after 12 months)

Physicians: influence on physicians knowledge about obesity, stigma (Fat Phobia Scale), satisfaction of general practitioners with their counseling behavior regarding weight management; Assessment at 2 points in time (start of study, after 12 months)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Doctor's Practice **Leipzig, deutschlandweit**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/02/03**
- Target Sample Size: **134**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **60 Years**

Additional Inclusion Criteria

Patients: BMI \geq 30, German as native language

Exclusion criteria

Patients: BMI <30, acute physical or mental illness that require immediate care and make study participation impossible according to the GP

Addresses

- **Primary Sponsor**

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 (BMBF)

D-10117 Berlin

Germany



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URL: [---]*

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2017/09/13**

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.