

## Trial Description

### Title

**Integrative psychosocial treatment program for patients with diabetes type I and type II (psy-PAD) - evaluation of an interdisciplinary psychosocial care model**

### Trial Acronym

[---]\*

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**For many patients with diabetes it is difficult to treat their disease properly and to follow recommendations and arrangements in order to change their lifestyles. This is especially difficult if there are mental and social strains at the same time. Different studies could show that these strains have a negative impact on the treatment of diabetes. In the present study, patients are able to discover obstacles concerning the handling of diabetes with the help of a physician specialized in psychosomatics or a psychologist in order to define and realize attainable goals. The dialogue being offered is viewed as “coaching” and includes 8 individual sessions within a period of 6 months. The study has a randomized-controlled design. The main target variable is the long-time blood glucose value (HbA1c). In addition, questionnaires on quality of life and on mental and psychosocial well-being are being used. Testing is taking place at 3 dates: at the beginning of the study, 6 months later, and 12 months later.**

### Brief Summary in Scientific Language

**In the present study, the exemplary implementation of an integrative psychosocial treatment program for patients with diabetes type I and type II (psy-PAD) with unsatisfactory blood glucose values shall be examined and evaluated regarding to their blood glucose control as well as the individual therapeutic goal attainment with respect to the patients' quality of life and their psychosocial strains. Cost-effectiveness is also being analyzed as well as the work satisfaction of the physicians. The study is realized as RCT in diabetic outpatient clinics. Patients in the intervention group receive psy-PAD, the control group receives an optimized standard care. Psy-PAD includes a manualized coaching and treatment program being conducted by psychotherapists in diabetic outpatient clinics in collaboration with diabetologists.**

## Organizational Data

- DRKS-ID: **DRKS00003247**
- Date of Registration in DRKS: **2011/11/28**
- Date of Registration in Partner Registry or other Primary Registry: [---]\*



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- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **163/09 , Ethik-Kommission des Fachbereichs Medizin der Justus-Liebig-Universität Gießen**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **E10 - Insulin-dependent diabetes mellitus**
- Free text: **psychosocial stress**
- ICD10: **E11 - Non-insulin-dependent diabetes mellitus**

## Interventions/Observational Groups

- Arm 1: **Intervention group (psy-PAD Patients in the intervention group receive psy-PAD; Psy-PAD includes a manualized coaching and treatment program being conducted by psychotherapists in diabetic outpatient clinics in collaboration with diabetologists.)**
- Arm 2: **Control group (optimized standard care)**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]\*
- Allocation: **Randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: [---]\*
- Control: **Active control**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**

Study Type: **Interventional**

Study Type Non-Interventional: [---]\*

Allocation: **Randomized controlled trial**

Blinding: **Open (masking not used)**

Who is blinded: [---]\*

Control: **Active control**

Purpose: **Treatment**

Assignment: **Parallel**

Phase: **N/A**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]\*

### Primary Outcome

**HbA1c at follow-up (6 months, 12 months)**

### Secondary Outcome

**Triglycerides, BMI, blood pressure, health-related quality of life (SF-36), manifestation of mental and psychosocial problems (PAID, HADS, PHQ-D short form), degree of attainment of individual therapeutic goals (GAS). Explorative: increase of the work satisfaction of the physician. Testing is taking place at 3 dates: at the beginning of the study, 6 months later, and 12 months later.**

### Countries of recruitment

- **DE Germany**

### Locations of Recruitment

### Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/11/28**
- Target Sample Size: **150**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **70 Years**

### Additional Inclusion Criteria

**Patients with secured diabetes type I and type II; HbA1c  $\geq 7, 5\%$ ; increased emotional stress scores (PAID-Score $>33$ , PAID-K-Score $\geq 6$ , WHO-5-Score $\leq 13$  or perceived as very stressed by the therapeutic team); age 18-70 years; treatment in a diabetic outpatient clinics; completed diabetes training; written informed consent**

### Exclusion criteria

**Patients with (a) severe comorbid physical diseases (e.g., advanced oncologic diseases), (b) severe mental diseases (dementia, severe depressive episode, psychosis, addiction), (c) inadequate knowledge of German language**

### Addresses

#### ■ Primary Sponsor

**Klinik für Psychosomatik und Psychotherapie der Justus-Liebig-Universität  
Giessen  
Mr. Prof. Dr. med. Johannes Kruse  
Friedrichstr. 33  
35392 Giessen  
Germany**

Telephone: **0641/98545600**

Fax: **0641/98545609**

E-mail: **Johannes.Kruse at psycho.med.uni-giessen.de**

URL: [---]\*

#### ■ Contact for Scientific Queries

**Klinik für Psychosomatik und Psychotherapie der Justus-Liebig-Universität  
Giessen  
Mr. Prof. Dr. med. Johannes Kruse  
Friedrichstr. 33  
35392 Giessen  
Germany**

Telephone: **0641/98545600**

Fax: **0641/98545609**

E-mail: **Johannes.Kruse at psycho.med.uni-giessen.de**

URL: [---]\*



### ■ Contact for Public Queries

**Klinik für Psychosomatik und Psychotherapie der Justus-Liebig-Universität  
Gießen**

**Ms. Dipl.-Psych. Birgit Köhler**

**Ludwigstr. 76**

**35392 Gießen**

**Germany**

Telephone: **0641/9945641**

Fax: **0641/9945617**

E-mail: **Birgit.Koehler at psycho.med.uni-giessen.de**

URL: [---]\*

## 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.)**

**Bundesärztekammer**

**Herbert-Lewin-Platz 1**

**10623 Berlin**

**Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

## Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): [---]\*

## 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.