



## Trial Description

### Title

**A lifestyle intervention program for patients with localized prostate cancer - a feasibility study**

### Trial Acronym

[---]\*

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**Prostatectomies can be accompanied by severe side effects including erectile dysfunctions or incontinence. Active surveillance as a treatment options gains importance especially for patients with localized prostate cancer. A healthy lifestyle including physical activity, healthy nutrition and stress management can enhance the quality of life of patients and may be beneficial for prognosis. There are only limited concrete lifestyle intervention options for these patients so far. The aim of the study is the assessment of the feasibility.**

### Brief Summary in Scientific Language

**Prostatectomies can be accompanied by severe side effects including erectile dysfunctions or incontinence. Active surveillance as a treatment options gains importance especially for patients with localized prostate cancer. A healthy lifestyle based on mind-body-medicine principles as well as naturopathy/complementary and alternative medicine including physical activity, healthy nutrition and stress management can enhance the quality of life of patients and may be beneficial for prognosis. There are only limited concrete lifestyle intervention options for these patients so far. The aim of the study is the assessment of the feasibility.**

## Organizational Data

- DRKS-ID: **DRKS00005795**
- Date of Registration in DRKS: **2014/02/19**
- 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.: **14-5693-BO , Ethik-Kommission der Medizinischen Fakultät der Universität Duisburg-Essen**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **C61 - Malignant neoplasm of prostate**

## Interventions/Observational Groups

- Arm 1: **lifestyle modification program (nutrition, physical exercise, relaxation, cognitive restructuring), 11 weeks, 6hrs/week**  
**+ home-based exercises**

## Characteristics

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

## Primary Outcome

**compliance / adherence during intervention period (diary, attendance time)**

## Secondary Outcome

**questionnaires:**  
**HRQoL (FACT-G, FACT-P)**  
**anxiety (STAI)**  
**depression (BDI)**  
**mindfulness (FFA)**  
**stress (PSS)**  
**barriers**  
**lifestly**



### **coping (COPE)**

**Other:**

**saliva cortisol**

**pro- and anti-inflammatory cytonkines (plasma)**

**all post-intervention (11 weeks)**

## **Countries of recruitment**

- DE **Germany**

## **Locations of Recruitment**

- Medical Center **Klinik für Naturheilkunde und Integrative Medizin, Essen**

## **Recruitment**

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/03/03**
- Target Sample Size: **20**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

### **Inclusion Criteria**

- Gender: **Male**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

### **Additional Inclusion Criteria**

- **PSA  $\leq$  10 ng/ml**
- **Gleason-Score  $\leq$  6**
- **cT1c and cT2a**
- **tumor in  $\leq$  2 punch biopsies (min. 8 punch biopsies )**
- **$\leq$  50 % tumor / punch biopsy**
- **life expectancy min. 10 yrs**
- **Karnofsky-Index min. 80% or ECOG-Performance-Status 0-2**
- **written informed consent**

### **Exclusion criteria**

- **previous or planned partial oder radical prostatectomy**
- **unsufficient knowledge of German language,**
- **severe physical or psychological diseases that may constrain patients**
- **systemic-neurological diseases (MS, parkinson, dementia).**

## Addresses

### ■ Primary Sponsor

**Universität Duisburg-Essen  
Lehrstuhl und Klinik für Naturheilkund und Integrative Medizin,  
Knappschafts-Krankenhaus,  
Kliniken Essen-Mitte  
Mr. Prof. Dr. med. Gustav Dobos  
Am Deimelsberg 34a  
45276 Essen  
Germany**

Telephone: **0049 - (0)201 174 25001**

Fax: **0049 - (0)201 174 25000**

E-mail: **gustav.dobos at uni-duisburg-essen.de; g.dobos at kliniken-essen-  
mitte.de**

URL: [---]\*

### ■ Contact for Scientific Queries

**Universität Duisburg-Essen,  
Lehrstuhl und Klinik für Naturheilkunde und Integrative Medizin,  
Knappschafts-Krankenhaus,  
Kliniken Essen-Mitte  
Mr. Prof. Gustav Dobos  
Am Deimelsberg 34a  
45276 Essen  
Germany**

Telephone: **0049-(0)201 174 25001**

Fax: **0049-(0)201 174 25000**

E-mail: **g.dobos at kliniken-essen-mitte.de**

URL: [---]\*

### ■ Contact for Public Queries

**Universität Duisburg-Essen,  
Lehrstuhl und Klinik für Naturheilkunde und Integrative Medizin,  
Knappschafts-Krankenhaus,  
Kliniken Essen-Mitte  
Mr. Prof. Gustav Dobos  
Am Deimelsberg 34a  
45276 Essen  
Germany**

Telephone: **0049-(0)201 174 25001**

Fax: **0049-(0)201 174 25000**



### Contact for Public Queries

**Universität Duisburg-Essen,  
Lehrstuhl und Klinik für Naturheilkunde und Integrative Medizin,  
Knappschafts-Krankenhaus,  
Kliniken Essen-Mitte  
Mr. Prof. Gustav Dobos  
Am Deimelsberg 34a  
45276 Essen  
Germany**

Telephone: **0049-(0)201 174 25001**

Fax: **0049-(0)201 174 25000**

E-mail: **g.dobos at kliniken-essen-mitte.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.)**

**Landeszentrum Gesundheit NRW  
Gesundheitscampus-Süd 9  
44801 Bochum  
Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

### Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2014/10/04**

### Trial Publications, Results and other documents

- Abstract **Society for Integrative Oncology 2016**

DRKS-ID: **DRKS00005795**

Date of Registration in DRKS: **2014/02/19**

Date of Registration in Partner Registry or other Primary Registry: [---]\*



Deutsches Register  
Klinischer Studien

German Clinical  
Trials Register

---

*Please note:*

*There are additional attributes available concerning this trial. To open an extended view please [click here](#).*