



Trial Description

Title

Implementation and evaluation of a home-based training and care program for physical and mental stabilization in colorectal, breast and prostate cancer - telemonitoring and self-management

Trial Acronym

CRBP-TS

URL of the trial

[---]*

Brief Summary in Lay Language

Prostate cancer, breast cancer and colorectal cancer are frequent malignant tumor diseases in men and women, with approximately 60,000 to 70,000 new cases each per year.

The causes for the development of cancer are multiple and in wide parts unclear. Genetic factors, environmental influences and eating habits play a role. Regular physical exercise is one of the most effective forms of prevention of colon, breast and prostate cancer (CRBP). For adults, at least 150 minutes of moderate or 75 minutes of intensive exercise per week is recommended for cancer prevention. Several studies have shown a reduction in tumour-specific mortality and recurrence of the tumour disease by 20 to 40% due to physical exercise.

The CRBP-TS care project combines online-supported physical training and the automated recording of activity and performance parameters with an electronic case file (ESF) accessible by the patient and treating physicians, in which the data obtained are presented.

The short and medium-term aims of CRBP-TS are to increase performance, muscle mass, reduce fat tissue, improve quality of life and reduce depression. The long-term goal is the reduction of tumour-specific and general mortality.

Brief Summary in Scientific Language

Prostate cancer and breast cancer are the most frequent malignant tumor diseases in men and women, with approximately 60,000 to 70,000 new incidences each year. Colorectal carcinoma affects women and men with a total of approx. 60,000 new cases per year and the trend is rising. There are multiple causes for the development of cancer and often unknown.

Regular physical exercise is one of the most effective primary and secondary forms of prevention. Part of the guidelines for the individual tumor entities is therefore the systematic application of physical training in the postoperative therapy. Overall, a representative number of meta-studies prove the effectiveness of training for colorectal, mammary and prostate carcinoma (CRBP). Combined endurance and strength training are an effective, supportive therapy in addition to conventional treatments, with a strong reduction of short- and medium-term tumor complications as well as tumor-specific morbidity and recurrence or metastasis rates. The risk reduction due to training is assumed to be approx. 20-40% for CRBP carcinomas. The available studies are mainly based on



questionnaire surveys using instructions for lifestyle changes and a qualitative implementation of the training programs with subjective assessment of the intensity. Despite the strong evidence base and the impressive preventive, protective and regenerative efficiency of physical training, there is no systematic implementation strategy or care structure in certified tumor therapy. The CRBP-TS project addresses this situation and combines online-based training and automated recording of activity and performance parameters with cross-sectoral bi-directional data evaluation and online communication via an electronic case file (ESF) accessible by the patient and treating physician.

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

No

Description IPD sharing plan

Data are published via publications; study protocol, data analysis and raw data can be made available via the authors.

Organizational Data

- DRKS-ID: **DRKS00020499**
- Date of Registration in DRKS: **2020/03/17**
- 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.: **056/20-ek , Ethikkommission an der Medizinischen Fakultät der Universität Leipzig**

Secondary IDs

Health condition or Problem studied

- ICD10: **C18 - Malignant neoplasm of colon**
- ICD10: **C19 - Malignant neoplasm of rectosigmoid junction**
- ICD10: **C20 - Malignant neoplasm of rectum**
- ICD10: **C50 - Malignant neoplasm of breast**
- ICD10: **C61 - Malignant neoplasm of prostate**

Interventions/Observational Groups



- Arm 1: **Individualized (at least 3 per week over 30 min) strength/endurance training by an online video presentation and 1 per week of outdoor training (depending on the patient, jogging, walking, cycling, fitness facilities, rehabilitation sports, etc.).**
- Arm 2: **Control group receives standard care according to current guidelines.**

Characteristics

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

Primary Outcome

Patients in the IG have a 13% higher VO2max after 6 months of intervention.

Secondary Outcome

- **significant improvement in the results of tumour-specific accompanying measurements (liquid biopsy, CTC, cfDNA, ctDNA, microRNA) and tumour markers**
- **significant reduction of hospitalizations by 15% in the IG compared to the KG**
- **significant improvement of quality of life, fatigue, depression (improvement of scores by 10%)**
- **increase of the energy consumption by 500 kcal (or 500 met/min) per week in the IG compared to the KG**
- **increase in patient compliance in the IG (95%) compared to the KG**

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- University Medical Center **Universitätsklinikum Leipzig, Leipzig**
- University Medical Center **Medizinische Hochschule Hannover, Hannover**



- University Medical Center **Universitätsklinikum Dresden, Dresden**
- Medical Center **Sana Klinikum Borna, Borna**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2020/07/01**
- Target Sample Size: **300**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **75 Years**

Additional Inclusion Criteria

- **Patients according to TNM status (UICC 8th. Ed.) for tumor resection of the primary case (carcinomas ICD): C18/19/20 colorectal, C50 breast, C61 prostate.**
- **T-stage: T1 to T3; N-stage: each N; M-stage: M0. In addition, patients with pre-surgical neoadjuvant pre-treatment as well as distant metastases (M1 stage) can be included in synchronous or metachronous RO resection (regarding primary tumor) and without intermediate chemotherapy.**
- **Age between 18 and 75 years**
- **ECOG congestion of 1 or better and without acute cardiac, renal, hepatic, endocrine, bone marrow or cerebral impairment**

Exclusion criteria

- **Complications after tumor surgery, which prolong the convalescence and limit the physical activity relevant for the program**
- **Presence of a second malignant tumour if therapy was less than 5 years ago**
- **Contraindication for the sports programme: orthopaedic, rheumatological, cardiovascular or neurological diseases and muscular diseases**
- **Any acute and active disease that prevents the termination of participation in the study**
- **Active alcohol abuse and consumption of illegal drugs within the last 6 months before inclusion in the study**
- **Lack of patient compliance**

Addresses

- **Primary Sponsor**
University Leipzig, Institute of Sport Medicine & Prevention

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 planned**
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

Please note:

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