**Trial Description**

**Title**

Multimodal therapy concept and aerobic training in breast cancer patients with chronic cancer-related fatigue syndrome (CRF): a comprehensive cohort design study

**Trial Acronym**

CRF-study

**URL of the trial**

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**Brief Summary in Lay Language**

We provide a new program for breast cancer patients with chronic cancer-related fatigue (non restorative and sustained tiredness). The program has been developed by the research institute Havelhöhe and the community hospital Havelhöhe, Berlin. The duration of the interventions is 10 weeks (one meeting/week). The multimodal therapies include optimization of sleep behavior, psychological talks, drawing therapy, eurythmic therapy and alternative or in combination with aerobic training. Our hypothesis is, that the multimodal therapy without aerobic training is so good like single aerobic training against the tiredness, the combination, maybe, will even better. The study participation is for free and will be realised at community hospital Havelhöhe in Berlin, at the medical university Hannover and at the university Witten/Herdecke.

Because of encouraging results which indicates a sustained improvement of the Cancer Fatigue Syndrom, we currently carry out a Follow-up after 4 years. The data collection started in May 2015 and will be finished not later than in March 2017. After that the data will be analysed.

**Brief Summary in Scientific Language**

Cancer-related fatigue (CRF) and sleep disorders are some of the most wearing and common symptoms in disease-free breast-cancer patients. Aerobic training is the treatment with the best available evidence, even though it seems to be insufficient with regards to improvements in cognitive fatigue. The research institute Havelhöhe and the community hospital Havelhöhe, Berlin, introduced a new multimodal therapy concept consisting of psycho-, sleep-education and new approaches based on anthroposophic medicine such as eurythmy and drawing therapy. The intervention of this study consists of a 10 week program with 10 meetings (once a week).

Primary parameters are the cancer fatigue scale (CFS-D), german version, and the
Pittsburgh Sleep Quality Index (PSQI). Another parameters are EORTC, Trait aR, State aR, scale for self-regulation, ICS and physical measurements. Our hypothesis is, that the multimodal therapy without aerobic training is as good as the single aerobic training against the cancer-related fatigue, the combination of both will be even better. The study participation is for free and will be realised at the community hospital Havelhöhe in Berlin, at the medical university Hannover and at the university Witten/Herdecke.

Because of encouraging results which indicates a sustained improvement of the combined primary outcome Fatigue/Sleep disturbance, but also other patient-related outcomes, we currently carry out a Follow-up after 4 years. For this we have made an amendment and we also have positive votes of the respective ethic comittees. In addition to a questionnaire on the health situation after four years, only questionnaires are provided which were collected at earlier times in the context of the study. The data collection started in May 2015 and will be finished not later than in March 2017. The data will be evaluated after finishing the data collection.

Organizational Data

- DRKS-ID: **DRKS00003736**
- Date of Registration in DRKS: **2012/06/19**
- 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.: **Eth-06/11, Ethik-Kommission der Ärztekammer Berlin**

Secondary IDs

- Free text: **breast cancer patients with fatigue-syndrom**
- ICD10: **G93.3 - Postviral fatigue syndrome**

Health condition or Problem studied

- Arm 1: **aerobic training, minimum 30 minutes, once a week, 10 interventions**
- Arm 2: **multimodal therapy, minimum 30 minutes, once a week, 10 interventions**
- Arm 3: **multimodal therapy + aerobic training, minimum 30 minutes, once a**
Characteristics

- Study Type: Interventional
- Study Type Non-Interventional: [---]*
- Allocation: Randomized controlled trial
- Blinding: [---]*
- Who is blinded: [---]*
- 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

Cancer Fatigue Scale (CFS-D), german version:
data collection: first intervention, last intervention, 6 months after last intervention

Pittsburgh Sleep Quality Index (PSQI):
data collection: first intervention, last intervention, 6 months after last intervention

Secondary Outcome

Quality of life index with EORTC QLQ-C30, time of measurement: first intervention, last intervention, 6 months after last intervention.
General vegetative status with Trait aR, time of measurement: first intervention, last intervention, 6 months after last intervention.
Actual vegetative status with State aR, time of measurement: first intervention, last intervention, 6 months after last intervention.
Anxiety and Depression with Hospital Anxiety and Depression Scale (HADS), time of measurement: first intervention, last intervention, 6 months after last intervention.
Self-regulation with Scale of self-regulation, time of measurement: first intervention, last intervention, 6 months after last intervention.
Internal coherence with ICS, time of measurement: first intervention, last intervention, 6 months after last intervention.
Mental participation of eurythmics with Bewegung und innere Kongruenz (ICPH, Version 2.1), time of measurement: last intervention and 6 months after last intervention.
Mental participation of drawing therapy with Innere Kongruenz und Einklang mit der Therapie (ICPTh, Version 1.0), time of measurement: last intervention and 6 months after last intervention.
Physiologic measurements: rhythm of rest and activity with 72-hours-Aktimeter and 24-hours-ECG, time of measurement: 0-3 weeks before first intervention, 0-3 weeks after last intervention.
Scales for therapists:
erythmics: HFET-2, time of measurement: 0-3 weeks before first intervention, 0-3 weeks after last intervention.
drawing therapy: AKT-DIAG, time of measurement: first intervention, 0-3 weeks after last intervention.

Countries of recruitment

- DE Germany

Locations of Recruitment

- Medical Center Gemeinschaftskrankenhaus Havelhöhe, Berlin
- University Medical Center Medizinische Hochschule Hannover (MHH), Klinik für Rehabilitationsmedizin, Hannover
- University Medical Center Private Universität Witten/Herdecke, Witten/Herdecke

Recruitment

- Planned/Actual: Actual
- (Anticipated or Actual) Date of First Enrollment: 2011/06/22
- Target Sample Size: 114
- Monocenter/Multicenter trial: Multicenter trial
- National/International: National

Inclusion Criteria

- Gender: Female
- Minimum Age: 18 Years
- Maximum Age: 75 Years

Additional Inclusion Criteria

- Not any chemotherapy, radiotherapy, surgery in the last 6 month. Final diagnosis from June 2009.

Exclusion criteria

- untreated cardiac, thyroid, nephric desease or untreated circulatory disorder

Addresses
DRKS-ID: **DRKS00003736**

Date of Registration in DRKS: **2012/06/19**

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

![Image](428x764 to 538x814)

**Primary Sponsor**

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**Sources of Monetary or Material Support**

**Private sponsorship (foundations, study societies, etc.)**

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Private sponsorship (foundations, study societies, etc.)

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URL: [---]*

Status

- Recruitment Status: Recruiting complete, follow-up continuing
- 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.