Trial Description

Title

Prospective, randomized, controlled study to evaluate the direct effect of specific movement therapy with professional supervision by various Inteventionen on the Fatigue Syndrome

Trial Acronym

FatiGo-Study

URL of the trial

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Brief Summary in Lay Language

The Fatigo study should investigate the immediate effectiveness of supervised and targeted exercise therapy on the Fatigue Syndrome.

Brief Summary in Scientific Language

Prospective, randomized, controlled study to evaluate the direct effect targeted movement therapy on fatigue syndrome. A total of 120 patients will be divided into five groups. Here, endurance and power groups differ with each moderate and high intensity and a control group. The training is supervised and located in the Oncology Training and Exercise therapy over a period of 4 weeks.

Organizational Data

- DRKS-ID: **DRKS00007798**
- Date of Registration in DRKS: **2015/05/05**
- 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.: **43/2015 , Ethikkommission der Deutschen Sporthochschule Köln**

Secondary IDs

Health condition or Problem studied

- ICD10: **F48.0 - Neurasthenia**
- Free text: **Fatigue**

Interventions/Observational Groups

- Arm 1: **Control group (there will be no training, but patients fill about 4 week the questionnaires and can then work on the OTT)**
- Arm 2: **strength group (moderate intensity of 50-60%, the training takes place 3 times a week 30 minutes over a period of 4 weeks)**
- Arm 3: **endurance group (moderate intensit 50-60%, the training takes place 3 times a week 30 minutes over a period of 4 weeks))**
- Arm 4: **Strength group (high intensity 70-80%, the training takes place 3 times a week 30 minutes over a period of 4 weeks)**
- Arm 5: **endurance group (high intensity 70-80%, the training takes place 3 times a week 30 minutes over a period of 4 weeks)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **assessor, data analyst**
- Control: **Active control (effective treament of control group), Control group receives no treatment**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The aim of this study is to evaluate the immediate effectiveness of targeted exercise therapy with professional supervision by various interventions on fatigue syndrome.

1 HADS
The HADS questionnaire was developed in studies with cancer patients to psychological well-being to be determined. The items include questions to anxiety and depression. In the end, two subscales HADS-D anxiety resulting value is the sum A1 to A7 and HADS-Depression S-value = sum D1 to D7. The questionnaire is filled in at preassesment and at the final testing (after the 4 weeks of training).

10.3.2 MFI20
This is an evaluation sheet for fatigue symptoms. The questionnaire consists of 20 questions (true yes, that too) on a scale of 1 to 5 (no, this is not true) to be answered. The questionnaire should be filled out once a week.

10.3.3. Freiburg Questionnaire
This questionnaire focuses on physical activity. The questionnaire-hold 8 questions which asked for the physical activities of the last week. The questions must be answered with "yes" and "no" and "frequency". At the end there is a total score and a sports score, which can be divided into three different categories. The questionnaire to be filled out once a week.

10.3.4 VAS
all patients are interrogated by the VAS scale 3 times a day during the 4 weeks of trianing (1 hour, 5 hours, and 10 hours after getting up and before and after each workout)how the fatigue state is. Participation gutters cross this on a scale from 1 to 10 on their current state of mind.

Instead of movement diary, which should be filedl out additional from patients everyday, they can also (if enough available) get a Senseware band. This keeps track of important physiological parameters.

Secondary Outcome

1. What intervention group and what intensity has the best effect on the Fatigue Syndrome?
2. What blood parameters play a role in fatigue?
3. Development of a training standard therapy

Assessments:
MFI20 = Fatigue
VAS = Fatigue
HADS = anxiety / depression
h1RM = force
Spiroergometry = endurance
Freiburg Questionnaire / Senseware / movement diary = physical activity
Blood sample = BDNF, IL-6, TNF alpha, VEGF, IGF1, MIF

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Köln**
- Doctor's Practice **Köln**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/04/14**
- Target Sample Size: **125**
- 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 with a history of malignancy (all entities)
Patients in the follow-up
Fatigue VAS 1-7
completed chemotherapy
Age> = 18 years
written and valid informed consent

Exclusion criteria

Fatigue Syndrome> 7;
Age> 75 years;
palliative patients with advanced cancer;
ongoing chemotherapy:
other diseases cause a fatigue;
more than three METS for a typical week (from Freiburg FB SHort version):
all disease situations that do not allow a sporting activity, in particular:
clinically overt cardiac failure (NYHA III-IV),
respiratory globally and partialinsuffizient,
persistent thrombocytopenia, congenital or acquired thrombocytopenia or any coagulation disorder;
unwillingness to storage and disclosure of personal health data in the context of the Protocol;
symptomatic coronary artery disease;
severe intractable hypertension;
not adjustable COPD;
uncontrolled cerebral seizures;
metastases;
Participation in another study sports;
medical or psychological condition that does not allow in the opinion of the investigator, that the patient participates in the study or gives a final signature of consent.

Addresses

- **Primary Sponsor**

Primary Sponsor

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■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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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.*