

# The effects of a 2-week whole-body electromyostimulation in cancer patients

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| <b>Submission date</b><br>06/11/2024   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>07/11/2024 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>10/01/2025       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### Background and study aims

Various studies show that regular physical activity is an efficient approach to increase medical therapy tolerance and may even improve its effectiveness in cancer patients. However, it is not always possible for patients to perform strenuous and time-consuming exercise programs. For that reason, whole-body electromyostimulation (WB-EMS) may be an interesting alternative form of exercise for cancer patients. In contrast to voluntary muscle contraction caused by small electrical impulses from the central nervous system, WB-EMS generates muscle contraction by an external EMS device. Therefore, the primary aim of this study was to examine whether 2 weeks of WB-EMS exercise are feasible and effective in cancer patients during medical treatment.

### Who can participate?

Patients aged over 18 years with different types of cancer and disease stages, undergoing acute therapy and after medical treatment

### What does the study involve?

Patients participated in supervised WB-EMS sessions four times over 2 weeks. Before and after the WB-EMS exercise period, patients were assessed regarding physical performance, body composition and patient-reported outcomes.

### What are the possible benefits and risks of participating?

The participants were able to try out a new exercise method over the course of the study's 2 weeks, which can be described as very time-efficient and not too strenuous. Besides the known risks associated with any physical activity, no additional risks were expected with this exercise method.

### Where is the study run from?

University of Cologne (Germany)

### When is the study starting and how long is it expected to run for?

May to September 2019

Who is funding the study?  
Investigator initiated and funded

Who is the main contact?  
Ms Jane Kersten, jane.kersten@uk-koeln.de

## Contact information

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Principal Investigator

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## **Additional identifiers**

### **EudraCT/CTIS number**

Nil known

### **IRAS number**

### **ClinicalTrials.gov number**

Nil known

### **Secondary identifying numbers**

17-165

## **Study information**

### **Scientific Title**

Short-term whole-body electromyostimulation in cancer patients: a single-arm trial

### **Study objectives**

Whole-body electromyostimulation (WB-EMS) could be an interesting and promising exercise technology for cancer patients, even for shorter periods such as the prehabilitation phase.

As an effective and beginner-friendly exercise method, WB-EMS could be considered in patients whose operation is imminent.

The primary aim of this study was to examine whether 2 weeks of WB-EMS exercise are feasible and effective in cancer patients during medical treatment.

As a secondary objective, the study aimed to examine whether short-term WB-EMS could already have a positive impact on body composition, physical performance, quality of life, anxiety and depression, fatigue syndrome, and perceived physical condition

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

Approved 05/03/2018, Medizinische Fakultät der Universität zu Köln (Kerpener Straße 62, Cologne, 50937, Germany; +49 (0)221-478-82900; ek-med@uni-koeln.de), ref: 17-165

### **Study design**

Single-arm non-randomized trial

**Primary study design**

Interventional

**Secondary study design**

Non randomised study

**Study setting(s)**

Fitness/sport facility, Hospital

**Study type(s)**

Prevention, Quality of life, Safety

**Participant information sheet**

Not available in web format, please use the contact details to request a participant information sheet

**Health condition(s) or problem(s) studied**

Cancer patients, with diverse entities, disease stages, under acute therapy and after medical treatment

**Interventions**

The patients performed four WB-EMS exercise sessions in 2 weeks. The training duration was 15 minutes in the first week, increasing to 17 minutes in the second week. The training was performed with an EMS device from Miha-Bodytech (Augsburg, Germany). During the electrical impulse stimulation, patients performed active body-weight movements such as Squats. The recovery time between two sessions was at least 48 hours.

**Intervention Type**

Device

**Pharmaceutical study type(s)**

Not Applicable

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

EMS device from Miha-Bodytech (Augsburg, Germany)

**Primary outcome measure**

Feasibility is measured using drop-out rate, training adherence and adverse events at the end of the intervention

**Secondary outcome measures**

1. Body composition measured using Bioelectrical Impedance Analysis (BIA) at baseline and post-test
2. Physical performance measured using modified step test according to the World Health Organization (WHO) scheme, the hypothetical one-repetition maximum and the handgrip method at baseline and post-test
3. Quality of life measured using the Quality-of-Life Questionnaire (EORTC-QLQ-C30) developed

by the European Organisation for Research and Treatment of Cancer at baseline and post-test

4. Anxiety and depressive symptoms measured using the Anxiety and Depression Scale at baseline and post-test
5. Fatigue syndrome measured using the Multidimensional Fatigue Inventory at baseline and post-test
6. Perceived physical condition measured using the German WKV-Questionnaire before and after every WB-EMS exercise session

**Overall study start date**

01/05/2019

**Completion date**

11/09/2019

## Eligibility

**Key inclusion criteria**

1. Diagnosed with a solid tumor
2. Receive concurrent medical therapy, including chemotherapy, radiation, immunotherapy or were cancer survivors, including receiving endocrine therapy
3. Over 18 years of age
4. Gave informed consent
5. Received medical clearance to exercise by a physician

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

15

**Total final enrolment**

13

**Key exclusion criteria**

1. Acute severe cardiovascular or neurological diseases
2. Patients with electrical implants (s.a. pacemaker or defibrillation)
3. Osteosynthesis-related metal in the body or ongoing pregnancy
4. Patients with acute venous thrombosis
5. Major surgeries in stimulation areas (e.g. heart surgery, abdominal or pelvic surgeries, orthopedic surgeries, neurosurgical procedures) within the last 3 months

**Date of first enrolment**

01/06/2019

**Date of final enrolment**

01/09/2019

## **Locations**

**Countries of recruitment**

Germany

**Study participating centre**

Center of Integrated Oncology Aachen Bonn Cologne Düsseldorf, University Hospital of Cologne

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## **Sponsor information**

**Organisation**

University Hospital Cologne

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**Sponsor type**

Hospital/treatment centre

**Website**

<https://www.cio-koeln-bonn.de/>

**ROR**

<https://ror.org/05mxhda18>

## **Funder(s)**

**Funder type**

Other

### Funder Name

Investigator initiated and funded

## Results and Publications

### Publication and dissemination plan

The study is planned to be published in the journal integrative cancer therapies.

### Intention to publish date

01/02/2025

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Jane Kersten (jane.kersten@uk-koeln.de)

### IPD sharing plan summary

Not expected to be made available

### Study outputs

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> |         | 07/01/2025   | 10/01/2025 | Yes            | No              |