

**PLEASE NOTE:** This study has been imported from ClinicalTrials.gov without additional data checks.

## Trial Description

### Title

**Comparison of the Effect of Whole-Body Electromyostimulation Versus High Intensity Resistance Exercise Training on Body Composition and Strength in Middle Aged Males**

### Trial Acronym

**EMSvsHIT**

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**The main aim of the study is to determine the effects of Whole-Body Electromyostimulation (WB-EMS) on body composition and muscle strength compared with the "golden standard" High Intensity Resistance Exercise Training (HIT) in healthy sedentary middle aged males.**

### Brief Summary in Scientific Language

[---]\*

## Organizational Data

- DRKS-ID: **DRKS00007261**
- Date of Registration in DRKS: **2016/02/29**
- Date of Registration in Partner Registry or other Primary Registry: **2014/03/03**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: [---]\*
- (leading) Ethics Committee Nr.: [---]\*

## Secondary IDs

- Primary Registry-ID: **NCT02078986 (ClinicalTrials.gov)**
- Sponsor-ID: **EMSVsHIT (University of Erlangen-Nürnberg Medical School)**
- Other Secondary-ID: **IMP\_FAU**

## Health condition or Problem studied

- Free text: **Healthy**
- Free text: **Sedentary**
- Free text: **Untrained**

## Interventions/Observational Groups

- Arm 1: **Other: Whole Body Electromyostimulation**
- Arm 2: **Other: High Intensity Resistance Exercise Training**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]\***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]\***
- Who is blinded: **assessor**
- Control: **Active control (effective treatment of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]\***

## Primary Outcome

- **Lean Body mass; time frame: 14 weeks (baseline to 14 week follow-up assessment); Lean Body Mass as assessed by Dual Energy x-Ray Absorptiometry (DXA) was determined twice, at baseline and after 14 weeks of exercise (WB-EMS or HIT)**

## Secondary Outcome

- **Appendicular Skeletal Muscle Mass; time frame: 14 weeks (baseline to 14 week follow-up assessment); Appendicular Skeletal Muscle Mass (ASMM) as assessed by**

**DXA was determined at baseline and after 14 weeks of exercise (WB-EMS or HIT)**

## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- **Institute of Medical Physics, University of Erlangen-Nuremberg, Erlangen**

## Recruitment

- Planned/Actual: [---]\*
- (Anticipated or Actual) Date of First Enrollment: **2014/02/27**
- Target Sample Size: **50**
- Monocenter/Multicenter trial: [---]\*
- National/International: [---]\*

## Inclusion Criteria

- Gender: **Male**
- Minimum Age: **25 Years**
- Maximum Age: **55 Years**

## Additional Inclusion Criteria

- **male, 25 to 55 years old**
  - **sedentary / untrained**
  - **Body Mass Index 20 - 30 kg/m<sup>2</sup>**

## Exclusion criteria

- **absent  $\geq$  2 weeks during the interventional period**
  - **medication or diseases with relevant impact on muscle metabolism**
  - **conditions that prevent WB-EMS (e.g. epilepsy, cardiac pacemaker)**
  - **severe neurological diseases**

## Addresses

### ■ Primary Sponsor

#### **University of Erlangen-Nürnberg Medical School**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

### ■ Contact for Scientific Queries

#### **Institute of Medical Physics, University of Erlangen-Nuremberg Wolfgang K Kemmler, PhD**

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### ■ Collaborator, Other Address

#### **Institute of Sports Medicine, Klinikum Nuremberg**

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### ■ Collaborator, Other Address

#### **Benevital Gesundheitspark, Herzogenaurach**

Telephone: [---]\*

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URL: [---]\*

## Sources of Monetary or Material Support

DRKS-ID: **DRKS00007261**

Date of Registration in DRKS: **2016/02/29**

Date of Registration in Partner Registry or other Primary Registry:  
**2014/03/03**

■ [---]\*

**Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

## Status

■ Recruitment Status: **Recruiting ongoing**

■ Study Closing (LPLV): [---]\*

## Trial Publications, Results and other documents

■ Further trial documents [---]\*

■ Further trial documents **Kemmler W, von Stengel S. Whole-body electromyostimulation as a means to impact muscle mass and abdominal body fat in lean, sedentary, older female adults: subanalysis of the TEST-III trial. Clin Interv Aging. 2013;8:1353-64. doi: 10.2147/CIA.S52337. Epub 2013 Oct 7.; 24130433**

■ Further trial documents **Kemmler W, von Stengel S. Alternative Exercise Technologies to Fight against Sarcopenia at Old Age: A Series of Studies and Review. J Aging Res. 2012;2012:109013. doi: 10.1155/2012/109013. Epub 2012 Feb 20.; 22500224**

■ Further trial documents **Kemmler W, Bebenek M, Engelke K, von Stengel S. Impact of whole-body electromyostimulation on body composition in elderly women at risk for sarcopenia: the Training and ElectroStimulation Trial (TEST-III). Age (Dordr). 2014 Feb;36(1):395-406. doi: 10.1007/s11357-013-9575-2. Epub 2013 Aug 16. PubMed PMID: 23949160; PubMed Central PMCID: PMC3889893.; 23949160**

*The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.*

*- Translation on version: 1*

*- Last processed date by ClinicalTrials.gov: 2014/11/05*

*\* 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.*