

Trial Description

Title

Psychological effects of a whole body electromyostimulation training - a randomized, controlled pilot study with healthy volunteers.

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Whole body electromyostimulation training (EMS) is applied in recreational / top sports, in the rehabilitation and geriatric field, in order to increase the muscular performance. The aim of the study is to investigate whether whole body electromyostimulation training has a positive effect on the condition and the current level of stress.

Brief Summary in Scientific Language

[---]*

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00012583**
- Date of Registration in DRKS: **2017/06/22**
- 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**

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Investigator Sponsored/Initiated Trial (IST/IIT): **yes**

Ethics Approval/Approval of the Ethics Committee: **Approved**

- (leading) Ethics Committee Nr.: **EA2/082/17 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

- Free text: **Healthy volunteers.**

Interventions/Observational Groups

- Arm 1: **Training condition A corresponds to a conventional whole body electromyostimulation training. The total duration of the training session is 20 minutes. The washout phase between training conditions A and B resp. B and A is 7 days.**
- Arm 2: **Training condition B training without low-frequency electromyostimulation (but using the same EMS equipment and clothing).**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: **patient/subject**
- Control: **Placebo**
- Purpose: **Basic research/physiological study**
- Assignment: **Crossover**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Subjective well-being (measured by visual analogue scale) before/after intervention.

Secondary Outcome

Subjective relaxation (measured by visual analogue scale). Current condition (multi-dimensional assessment questionnaire MDBF by Steyer et al., 1997). Current degree of stress (Recovery Stress Questionnaires EBF by Kallus and Kellmann, 2016). Before/after intervention.

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- other **zwei Miha bodytec Elektromyostimulations-Fitnessstudios, Berlin**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/06/12**
- Target Sample Size: **25**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **65 Years**

Additional Inclusion Criteria

Healthy persons, who regularly exercise electromyostimulation training once or twice a week.

Exclusion criteria

Exclusion criteria are among others electronic pacemakers and generally electronic implants, acute inflammation, febrile diseases, cancer diseases, untreated arterial hypertension, thrombosis, bleeding or bleeding tendency, apoplexy, neurological disorders such as epilepsy, muscular dystrophies, paresis. Severe hepatic / renal disease.

Addresses

■ Primary Sponsor

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Sources of Monetary or Material Support

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

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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.