Trial Description

Title

Effects of whole body vibration in the elderly and in neurologic disorders

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Long term effects (up to one year) of whole body vibration. Aim of this study is to research the effects of different frequencies, sets, duration, times per week on motor symptoms, gait, mobility, balance, flexibility,... Randomized allocation to treatment or control group. Participants are blinded.

Brief Summary in Scientific Language

Effects of whole body vibration in the elderly and in neurologic disorders

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00012265**
- Date of Registration in DRKS: **2017/04/04**
- 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.: **16/12 , Ethikkommission der Universität des Saarlandes**

Secondary IDs

Health condition or Problem studied

- Free text: **Parkinson's Disease**
- Free text: **Multiple Sclerosis, Apoplex**
- ICD10: **G20 - Parkinson disease**
- ICD10: **G35 - Multiple sclerosis**
- ICD10: **I63 - Cerebral infarction**

Interventions/Observational Groups

- Arm 1: **Whole body vibration; different frequencies for treatment groups (6, 12, 18, and 24 Hz), times per week (1, 2, 3, or 4x/week), duration at least 4 weeks up to 1 year**
- Arm 2: **Placebo group: same setting as treatment group, without vibration standing on the platform, other parameters same as treatment group**
- Arm 3: **For all other questions: different frequencies (6, 12, 18, or 24 Hz), times per week (1, 2, 3, or 4x/week), different duration of sets and rests (60 sec/60 sec, 60 sec/120 sec)**
- Arm 4: **A further control group receives a classic program of physiotherapy without platform, times per weef and duration analogous to the treatment group**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, assessor**
- Control: **Placebo, Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Improvement after treatment over a few weeks for balance (Force plate: Sway path, and velocity, body position; Berg Balance Scale), mobility (Timed up and

Go), flexibility (Sit and reach),... Measurement before first treatment and 20 minutes after last treatment (after 4, 8, or 12 weeks), then follow-up after 1, 2, and 4 weeks

Secondary Outcome

[---]*

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Kliniken, Universität, KISS, Vereinsheime u. a., Saarland**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/04/20**
- Target Sample Size: **200**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **no minimum age**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Parkinson's Disease (confirmed), Multiple Sclerosis or Apoplex, no matter what duration and severity/stage of the disease; elderly who cannot participate on conventional physical training

Exclusion criteria

severe coronary heart disease, acute thrombosis, fracture, or knee or hip prosthesis (for less than 3 months), severe diabetes, arrhythmia, pacemaker, untreated hypertonia, open wounds on the soles

Addresses

■ **Primary Sponsor**

Sportwissenschaftliches Institut der Universität des Saarlandes
66123 Saarbrücken
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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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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.*