

**STUDY PROTOCOL**

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# Study protocol: the effect of whole body vibration on acute unilateral unstable lateral ankle sprain- a biphasic randomized controlled trial

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## Abstract

**Background:** Ankle sprains often result in ankle instability, which is most likely caused by damage to passive structures and neuromuscular impairment. Whole body vibration (WBV) is a neuromuscular training method improving those impaired neurologic parameters. The aim of this study is to compare the current gold standard functional treatment to functional treatment plus WBV in patients with acute unilateral unstable inversion ankle sprains.

**Methods/Design:** 60 patients, aged 18–40 years, presenting with an isolated, unilateral, acute unstable inversion ankle sprain will be included in this bicentric, biphasic, randomized controlled trial. Samples will be randomized by envelope drawing. All patients will be allowed early mobilization and pain-dependent weight bearing, limited functional immobilization by orthosis, PRICE, NSARDs as well as home and supervised physiotherapy. Supervised physical therapy will take place twice a week, for 30 minutes for a period of 6 weeks, following a standardized intervention protocol. During supervised physical therapy, the intervention group will perform exercises similar to those of the control group, on a side-alternating sinusoidal vibration platform. Two time-dependent primary outcome parameters will be assessed: short-term outcome after six weeks will be postural control quantified by the sway index; mid-term outcome after one year will be assessed by subjective instability, defined by the presence of giving-way attacks. Secondary outcome parameters include: return to pre-injury level of activities, residual pain, recurrence, objective instability, energy/coordination, Foot and Ankle Disability Index and EQ 5D.

**Discussion:** This is the first trial investigating the effects of WBV in patients with acute soft tissue injury. Inversion ankle sprains often result in ankle instability, which is most likely due to damage of neurological structures. Due to its unique, frequency dependent, influence on various neuromuscular parameters, WBV is a promising treatment method for patients with acute unstable inversion ankle sprains.

**Trial registration:** NCT01702597

**Keywords:** Whole body vibration, Ankle sprain, Rehabilitation, Functional treatment

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## Background

Lateral ankle sprains are one of the most common musculoskeletal injuries [1,2]. They mostly result from an internal rotation and adduction of the plantarflexed foot with subsequent damage to the lateral capsulo-ligamentous complex. About 65% of all lateral ankle sprains are isolated anterior tibio-fibular ligament (ATFL) injuries, while 20% are combined ATFL and calcano-fibular ligament injuries [3]. 85% of all ankle injuries are ankle sprains and 85% of those are inversion sprains [4], with about one ankle sprain occurring per 10.000 people every day [5]. Although usually considered an innocuous injury, three-year full recovery rates range from 36% to 85% [6].

Ankle instability is most likely caused by damage to passive structures and neuromuscular impairment [7]. Damage to passive structures, i.e. capsular structure and ligaments, results in objective (anterior drawer, talar tilt) and subjective instability (giving-way) [3]. Neurological impairments include muscle fatigue [7-9], reduced dynamic balance [10-12] and impaired postural control [13-15]. Although not all patients with functional (FAI) or chronic ankle instability (CAI) present with objective instability, they are all thought to have neuromuscular impairments [2,16,17]. This results in lower physical activity levels [18], diminished quality of life [19], and a possible increase in the risk of osteoarthritis [20,21].

Any treatment plan should therefore address both damaged passive structures and neuromuscular impairment. Generally, three treatment regimens are available: functional treatment (early mobilization and bracing), cast immobilization for 2–6 weeks, or operative treatment [22,23]. A Cochrane review from 2007 comparing conservative and surgical treatments found similar outcomes [3]. Therefore, functional treatment has to be considered the current gold standard. Functional treatment should allow healing of damaged passive structures and compensate for neuromuscular impairments, i.e. improve muscle strength and proprioception. Physical therapy therefore includes stretching, body-weight exercises, training apparatus and devices (for example wobble board training). Supervised rehabilitation has proven superior to conventional treatment [24,25].

A neuromuscular training method gaining increased attention is whole body vibration (WBV). WBV involves synchronous or side-alternating sinusoidal vibrations, which are transmitted to the body via platforms. It is believed to evoke muscle contractions via stretch reflexes in the muscle spindle system [26-28]. A growing body of evidence indicates improvements of various neuromuscular parameters following WBV, such as power, strength, movement velocity, range of motion and balance [29-38]. Reports to the contrary [39,40] may be due to heterogeneous patient populations and varying intervention protocols, which in turn can be due to limited knowledge of

the dose-effect relationship, i.e. vibration frequency and amplitude.

In general, frequencies <10Hz are believed to loosen muscle and tissue. Frequencies >10Hz and <20Hz still allow active contraction and relaxation of muscle fibers and are used for coordination exercises. Frequencies >20Hz result in isotonic muscle contraction [41]. Vibration amplitude seems to be positively correlated to muscle activity [42-44]. Although WBV has numerous contraindications, as listed in Table 1, the only adverse side effects reported are temporary hyposensitivity of the foot soles [45].

With WBV improving range of motion (ROM), power and balance - parameters known to be affected in patients with ankle instability - it might be beneficial to include it into the current functional treatment regime. To our knowledge only one study investigated the effects of WBV in patients with ankle instability. Cloak et al. [49] conducted a randomized controlled trial (RCT) on functional ankle instability in dancers (n=38), comparing WBV to a control group (regular dance training). The WBV group yielded significantly better results for balance (STAR extrusion balance test) as well as a significantly reduced Center of Pressure values.

## Aim of study

The aim of this bicentric, biphasic, randomized, controlled study is to compare current gold standard functional treatment to functional treatment plus WBV in patients with acute unilateral unstable inversion ankle sprains over a period of 12 months.

## Hypotheses

1. Short term results (after 6 weeks):  $H_0$  = Functional treatment in combination with WBV therapy in patients with acute unilateral unstable inversion ankle sprains does not improve the Sway-Index compared to functional treatment alone.
2. Mid-term results (after 12 months):  $H_0$  = Functional treatment in combination with WBV therapy in patients with acute unilateral unstable inversion ankle sprains does not result in a reduction of the recurrence rate compared to functional treatment alone.

## Methods/Design

### Study design and protocol

The study design is a bicentric, biphasic, randomized, controlled trial, following the CONSORT statement guidelines [50]. 60 patients will be randomized into an intervention (supervised functional treatment and WBV) or control group (supervised functional treatment). Intervention will take place twice a week at a rate of 30 minutes per session,

**Table 1 Inclusion- and exclusion criteria**

Inclusion criteria	Exclusion criteria
Age: 18 to 40 years	Pregnancy
Acute, unilateral, unstable, inversion ankle sprain (Grade II, III)	Conditions affecting the neuromuscular or musculoskeletal system
Signed informed consent	Previous surgical interventions to the foot, ankle, knee or hip; known FAI, CAI
Patient can read and understand German	Conditions possibly affecting balance
	Cardiovascular disease including thrombosis
	Respiratory diseases
	Abdominal diseases (including gallstones)
	Urological diseases (including kidney and bladder stones)
	Gynaecological diseases and + intrauterine devices
	Neurological diseases including epilepsy within the last 2 years
	Acute injuries to the head
	Patient is not available for follow-up visits
	Patient unable to give informed consent
	Patient suspected to be non-compliant

Functional classification system for lateral ankle sprains: Grade II: hematoma/swelling/pain on palpation and positive anterior drawer test (complete tear of the ATFL, incomplete tear of the CFL); Grade III: hematoma/swelling/pain on palpation and positive anterior drawer test and positive talar tilt test (complete tear of the ATFL and CFL); adapted from [46-48]; FAI: Functional ankle instability; CAI: Chronic ankle instability.

for 6 weeks. Figure 1 schematically illustrates the study protocol.

The study design is in accordance with the recommendations of the Declaration of Helsinki, and was approved by the Ethical Committee of the Medical University of Munich (#315-12) and the Medical University of Innsbruck (#UN4833). The study is registered as a randomized controlled trial (NCT01702597).

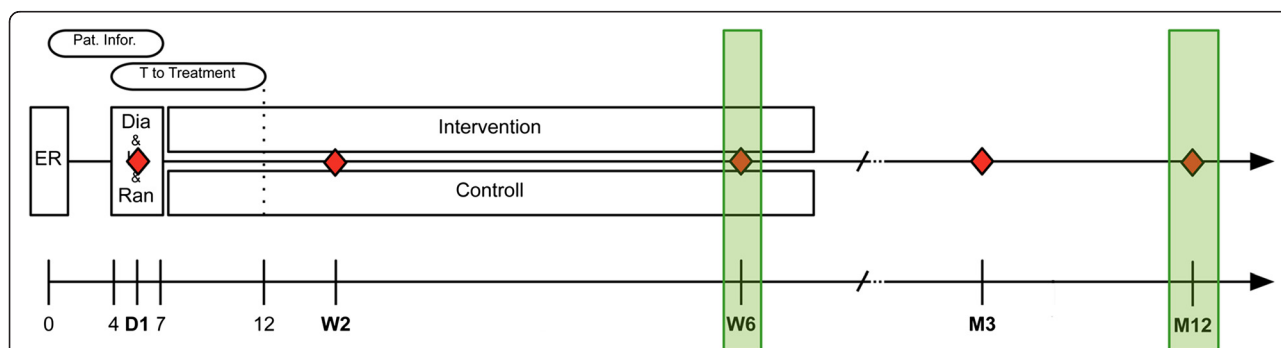
**Study centers, population, screening and randomization**

The study will be conducted at the Department of Surgery, Medical University of Munich (LMU), Germany, and the Department of Trauma Surgery, Medical University of Innsbruck, Austria. Patients will be screened within the regular emergency unit setting using a standardized algorithm for ankle sprains [51]. Patients presenting with an isolated, unilateral, acute unstable ankle sprain grade II or

III (as defined in Table 1), aged 18–40 years, will be informed about the study and potential risks before signing the informed consent. In case initial classification is not possible (i.e. patients do not tolerate medical examinations), patients will be invited for a delayed physical examination four to seven days following trauma. Inclusion and exclusion criteria are listed in Table 1. Within seven days, participating patients must be included and randomized by envelope drawing.

**Intervention**

All patients will be allowed early mobilization and pain-dependent weight bearing, functional immobilization by orthosis, PRICE (protection, rest, ice, compression, elevation), NSAIDs as well as home and supervised physiotherapy. Patients will receive a standardized hand-out for home training. Table 2 outlines the standardized



**Figure 1 Schematic illustration of the study protocol.** ER = Emergency Department; Dia & Inc & Ran = Diagnosis, inclusion and randomization of patient; Pat. inform = Patient information; T to Treatment = maximum time interval between patient inclusion and first treatment intervention; D = day; W = week; M = month; Red diamond = Patient visits; Green segments = short-term/mid-term analysis.

**Table 2 Detailed treatment protocol**

Lvl	Phases	Time	Symptoms	Treatment Goals	Physiotherapy:	
					CONTROL GROUP	INTERVENTION GROUP <sup>1</sup>
1	Inflam.	0 - 3d	<ul style="list-style-type: none"> <li>▪ Pain at rest</li> <li>▪ Swelling and hematoma</li> <li>▪ Pain during weight bearing</li> </ul>	<ul style="list-style-type: none"> <li>▪ Reduction of pain and swelling</li> <li>▪ Improvement of perfusion</li> <li>▪ Partial weight bearing</li> </ul>	<ul style="list-style-type: none"> <li>▪ PRICE</li> <li>▪ NSARDs</li> <li>▪ Pain-dependent weight bearing +/- crutches</li> <li>▪ Pain-dependent mobilization of the foot</li> <li>▪ No tape or brace (due to swelling)</li> </ul>	
2	Prolif.	4 - 10d	<ul style="list-style-type: none"> <li>▪ Foot can actively be put into neutral position</li> <li>▪ Reduction of swelling</li> <li>▪ Partial weight bearing without complete heel-to-toe movement</li> <li>▪ Possible fear of movement</li> </ul>	<ul style="list-style-type: none"> <li>▪ Restoring function</li> <li>▪ Restoring full weight bearing</li> </ul>	<ul style="list-style-type: none"> <li>▪ NSARDs</li> <li>▪ Pain-dependent weight bearing +/- crutches</li> <li>▪ Arch of foot / leg axis</li> <li>▪ Training of symmetrical gait and regular foot strike</li> <li>▪ Exercises to improve ROM, active stabilization, coordination and regular walking pattern</li> <li>▪ Brace</li> </ul>	<p>Frequency 10Hz / 16 Hz</p> <p>Amplitude: s. below</p> <p>Duration: 5min</p> <p>Exercises, vibration:</p> <ul style="list-style-type: none"> <li>▪ Gymnastic ball, feet parallel to mark 1 or 2, patient rolls forth and back, in order to Flex/Ext. in the upper ankle joint</li> <li>▪ Gymnastic ball, injured foot placed transverse on the WBV platform (ankle in-between mark 0 and 1), patient rolls forth and back, in order to flex/extent in the upper ankle joint</li> </ul> <p>Exercises, general:</p> <ul style="list-style-type: none"> <li>▪ Pain dependent weight bearing +/- Crutches</li> <li>▪ Walking motion training</li> </ul>
3	Early Remod.	11 - 21d	<ul style="list-style-type: none"> <li>▪ Residual hematoma</li> <li>▪ Normal heal-to-toe movement</li> <li>▪ Pain and fear of movement under load</li> </ul>	<ul style="list-style-type: none"> <li>▪ Improving muscular strength, and active/functional ankle stability, and ROM</li> <li>▪ Training regular walking pattern and climbing stairs</li> </ul>	<ul style="list-style-type: none"> <li>▪ Information on preventive measures (Brace)</li> <li>▪ Exercises to improve balance, ROM, muscle strength, walking pattern, running and climbing the stairs</li> <li>▪ Dynamic stability: stepwise increase of training intensity; switching from static to dynamic exercises</li> <li>▪ Guidance for home training</li> </ul>	<p>Frequency: &gt;10Hz, 18-24Hz</p> <p>Amplitude: 1-2,5mm</p> <p>Duration: 3 Sets a 3 Min with 2 Min break each</p> <p>Exercises, vibration:</p> <ol style="list-style-type: none"> <li>1) Dynamic squatting (warm-up)</li> <li>2) Dynamic squatting (increasing depth)</li> <li>3) Two leg stance with slightly bend knees, slow weight transfer (right ←→ left)</li> <li>4) One-leg squatting, transverse to WBV plate +/- support of the non-injured leg</li> </ol>

**Table 2 Detailed treatment protocol (Continued)**

4	Late Remod.	3 - 6wk	<ul style="list-style-type: none"> <li>▪ No hematoma</li> </ul>	<ul style="list-style-type: none"> <li>▪ Improvement of resistance during walking, running, climbing stairs</li> </ul>	<ul style="list-style-type: none"> <li>▪ Exercises to improve coordination (skipping, jumping, ...)</li> </ul>	<p>Exercises, general:</p> <ul style="list-style-type: none"> <li>▪ Guidance for home training</li> </ul> <p>Frequency: &gt;10Hz, 18-24Hz</p>
			<ul style="list-style-type: none"> <li>▪ Dorsal flexion possible</li> <li>▪ No more pain or fear of movement during sports</li> </ul>	<ul style="list-style-type: none"> <li>▪ Improvement of work/sports specific tasks</li> </ul>	<ul style="list-style-type: none"> <li>▪ Stepwise load increase and switching from static to dynamic / from simple to complex / from cyclic to non-cyclic exercises</li> <li>▪ Guidance for home training</li> </ul>	<p>Amplitude: 2-3mm</p> <p>Duration: 3 Sets a 3 Min with 2 Min break each</p> <p>Exercises, vibration:</p> <ol style="list-style-type: none"> <li>1) Dynamic squatting (warm-up)</li> <li>2) Side-skipping with flexed knees</li> <li>3) Calf raises</li> <li>4) Vibration on a tilted surface, elevated leg = uninjured leg</li> <li>5) Static squats (45° / 90°); Frequency 18+, Amplitude 2+</li> </ol> <p>Exercises, general:</p> <ul style="list-style-type: none"> <li>▪ Guidance for home training</li> </ul>

Lvl: Level; Phase: Healing phases; d: days; Remod.: Remodeling; Inflamm.: Inflammatory phase; Prolif.: Proliferation phase; wk: week; PRICE: Protection, Rest, Ice, Compression, Elevation; NSARDs: Non-steroidal anti-rheumatic drugs; ROM: Range of motion; min: Minutes; Hz: Herz; mm: Millimeter; WBV: Whole body vibration; Min: Minute.

supervised intervention protocol for both groups, taking into consideration the different soft tissue healing phases. The functional treatment protocol was developed based on treatment guidelines published by the Royal Dutch Society of Physical Therapy [52] and is similar to previous treatment protocols [53-56]. Patients will receive supervised physiotherapy twice a week for 6 weeks [57-59] with each session lasting 30 minutes. Patients will be asked to do home exercises according to the handout every second day.

The intervention group will use a sinusoidal side alternating vibration system (Galileo® Med M Plus, Novotec, Pforzheim, Germany) with a peak-to-peak displacement range from 0–9 with 5–30 Hz acceleration. They will perform similar exercises as the control group on the vibration platform and the overall session duration will be the same. The detailed WBV intervention protocol is presented in the Additional file 1.

Physiotherapists who will receive specific training for the WBV prior to this study will supervise all training sessions.

**Outcome parameters**

The in Table 3 outlined outcome parameters are the most frequently used in ankle sprain literature [3,22,25]. Neuro-muscular impairment will be assessed using a Leonardo

Mechanograph GRFP (16 bit, 800 Hz; NOVOTEC Medical GmbH, Germany) and are marked with a \* in Table 3. Each test will be performed following the manufacturer's instructions, with the patients not having participated in sports 24h prior to data acquisition. Tests will be conducted as soon as tolerated by patient.

**Sample size estimation and statistics**

With this study being the first using WBV with acutely injured patients, data to conduct sample size estimation is lacking. Therefore sample size was chosen according to previous studies on WBV or ankle instability [32,49, 61,62].

Statistical methods used will include descriptive statistics, Student's *t*-test and Fisher's exact test.

**Adverse events**

The only adverse side effects of WBV reported in literature were temporary hyposensitivity of the foot soles [45]. Possible adverse events related to the interventions include pain, fall from the WBV device/wobble board, and delayed mobilization or healing. Unexpected events related to data acquisition might be patients' inability to perform certain load-dependent examinations. Severe adverse events are only expected following a fall from the training device.

**Table 3 Complete list of outcome parameters**

<b>Primary Outcome parameter (1)</b>	
(short term; 6 weeks)	
Postural control: Balance Test (Sway Index)*	[numeric, scale]
<b>Primary Outcome parameter (2)</b>	
(mid-term; 1 year)	
Subjective Instability (Giving-way)	[dichotomous variable]
<b>Secondary Outcome parameters</b>	
Return to pre-injury level of activity (work, sports)	[dichotomous variable]
Residual pain:	
Pain at rest	[dichotomous variable; VAS]
Pain on weight-bearing	[dichotomous variable; VAS]
Pain during sports	[dichotomous variable; VAS]
Subjective Instability (Giving-way)	[dichotomous variable]
Recurrence	[dichotomous variable]
Objective instability:	
Anterior drawer	[dichotomous variable]
Talar tilt	[dichotomous variable]
Ankle ROM	[numeric, scale]
Postural control: Balance Test (Sway index)*	[numeric, scale]
Energy/coordination:	
Multiple one leg hopping*	[numeric, scale]
Single two leg jump*	[numeric, scale]
Complications	[text]
Scores:	
Foot and Ankle Disability Index [60]	[numeric, scale]
EQ 5D 5L	[numeric, scale]

## Discussion

The present study protocol on the effect of WBV in patients with acute, unilateral, unstable inversion ankle sprains is the first study to apply WBV in patients with acute soft tissue injuries. Due to its influence on various neuromuscular parameters, which are known to be impaired in patients with ankle instability, WBV provides a novel, functional treatment approach for this problem.

Several limitations of the present protocol must be discussed. First of all, the authors have decided to use a functional classification system. With ankle instability being the most important parameter for further treatment decision, an established functional classification system was chosen. Ankles are classified into stable or unstable based on clinical presentation and examination (swelling, anterior drawer test and talar tilt test) [46-48]. In case initial examination is not tolerated, delayed physical examination has been shown to be equal to arthrography (specificity/sensitivity: 85%/96%) [63-65]. Its feasibility in daily

practice and high sensitivity makes it a suitable classification system for patients with acute inversion ankle sprains.

Second, as discussed in the introduction, functional treatment seems to be the current gold standard treatment approach. Still, immobilization, as well as type and duration of physiotherapy are a matter of discussion. Kerkhoffs et al. [66] conducted a systematic review on the effectiveness of various braces/bracing methods for acute ankle sprains and found lace-up supports to be the most effective, which seems supported by a Cochrane Review [3]. A recent single-blinded RCT by Lamb et al. [67] found a short period of immobilization in an Aircast brace to result in faster recovery than double-layered tubular compression bandage. This is in line with a review by Kemle et al. [23] who found evidence pointing towards the superiority of ankle braces. Consequently, initial immobilization will be realized with an ankle brace. Moreover, the type and duration of functional rehabilitation remains unclear.

Our supervised rehabilitation protocol is based on the guidelines of the Royal Dutch Society of Physical Therapy [52], which is comparable to other published treatment protocols [53-57,68]. Although the optimal intensity of physical rehabilitation remains unclear, 45 minutes, twice to three times a week over a period of 6-8 weeks seem to be beneficial [10,57-59,69]. Due to administrative issues, we decided on supervised rehabilitation for 30 minutes, twice weekly for 6 weeks, with additional home exercises.

A third possible limitation are the chosen outcome parameters. Whereas power, assessed by a single leg vertical jump, has been proven significantly different between patients with recurrent ankle sprains and healthy controls [14,70-72], there is no consensus in literature as to which method best assesses balance. A commonly used method is center of pressure (COP) [73-76]. Whereas COP assessed during single leg stance with eyes open was ineffective in identifying patients with ankle instability [73,74], this could be achieved with single leg stance with eyes closed [75,76]. Furthermore, COP provides an objectively verifiable parameter. Other commonly used outcome parameters such as return to work or return to sports are parameters not necessarily coinciding with the recovery of the injured ankle. They highly depend on the patient's attitude, attitude, schedules and type of job/sport.

## Additional file

**Additional file 1: Detailed WBV treatment protocol.**

### Abbreviations

WBV: Whole Body Vibration; PRICE: Protection, Rest, Ice, Compression, Elevation; NSARDs: Non-Steroidal Antirheumatic Drugs; %: Percent; ATFL: Anterior Tibio-Fibular Ligament; FAI: Functional Ankle Instability; CAI: Chronic Ankle Instability; Hz: Herz; ROM: Range Of Motion; RCT: Randomized Controlled Trial; n: Number; H<sub>0</sub>: Hypothesis; h: Hour; COP: Center Of Pressure.

### Competing interest

The authors declare that they have no competing interests.

### Authors' contributions

SFB designed the study, was responsible for ethical approval of the LMU, Munich and prepared the manuscript. MW substantially contributed to the conception of the study protocol, was responsible for the ethical approval in Innsbruck and assisted in drafting the manuscript. HP had substantial input in the design of the study and revised the manuscript. MS (Dr. Sieb) substantially contributed to the conception of the study, revised the ethics proposal for Innsbruck and revised the manuscript. MR contributed to the design of the study, revised the ethics proposal for Munich and the manuscript. WM contributed to the design of the study, revised the ethics proposal for Munich and the manuscript. MS (Prof. Schieker) supervised the study protocol preparation and revised the manuscript. MB substantially contributed to the design of the study, was responsible for the ethics proposal for Innsbruck and revised the manuscript. All authors read and approved the final manuscript.

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