ISRCTN15769490 https://doi.org/10.1186/ISRCTN15769490

Influence of a vibrating therapeutic couch on pain level in healthy adults with back pain

Submission date
25/02/2023

Recruitment status
No longer recruiting

Registration date
07/07/2023

Overall study status
Completed

Last Edited
06/03/2026

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
One speaks of non-specific back pain when no cause can be found with simple clinical means that can easily explain the regional back pain. A possible form of physical therapy is vibration, which has an effect on the vascular system by increasing arterial blood flow, reducing vascular resistance, and expanding capillaries. Vibration affects the muscles and skin like strains during a massage. A high vibration intensity (frequency and amplitude) also affects peripheral blood circulation, metabolism and muscular regeneration. This study aimed to test the extent to which vibration, in addition to heat therapy, has an effect on non-specific back pain.

Who can participate?
Healthy adults aged between 18-80 years old with moderate to strong low back pain

What does the study involve?
The participant will visit the trial site on day one and after signing the patient information, the physician will gather general health information to confirm the patient's suitability for the study. After enrolling the patient into the study, baseline parameters will be captured followed by the study intervention. During the intervention period, the patient lies on a cushioned vibrating plate for about 10 minutes. After this procedure, the first post-intervention parameters are taken. On the following day, a check-up call is undertaken including pain reporting.

What are the possible benefits and risks of participating?
Possible benefits are regular health checks accompanied by a physician within a non-placebo-controlled study. Possible side effects include heat or vibration, and reflective irritation of the skin associated with slight redness and/or a slight itching of the skin. In very rare cases, slight but temporary nausea (vegetative dysregulation).

Where is the study run from?
Dr Hartard Physio Vibbing (Physiotherapy and MPG-Study Site) (Germany)

When is the study starting and how long is it expected to run for?
May 2014 to March 2016

Who is funding the study?
Kurperle GmbH, Bad Füssing (Germany)

Who is the main contact?
Principal Investigator, Dr. Dr. Med. Univ. Manfred Manfred Hartard, m.hartard@cdg-muenchen.de

Contact information

Type(s)
Principal investigator

Contact name
Dr Manfred Hartard

Contact details
Helene-Mayer-Ring 14/EE
Munich
Germany
80809
+498935747125
m.hartard@cdg-muenchen.de

Type(s)
Scientific

Contact name
Dr Study Clinic (Studienambulanz) Team

Contact details
Helene-Mayer-Ring 14/EE
München
Germany
80809
+498935819977
studienambulanz@cdg-muenchen.de

Type(s)
Public

Contact name
Dr Study Clinic (Studienambulanz) Team

Contact details
Helene-Mayer-Ring 14/EE
München
Germany
80809
+498935819977
studienambulanz@cdg-muenchen.de

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
VAS-OXY-BIGESTA SPINTRAC MEDICAL

Study information

Scientific Title
Influence of resting on a vibrating or heating plate on pain level and peripheral oxygen saturation in patients aged 18 to 80 with nonspecific back pain

Acronym
BIGESTA

Study objectives
Resting on a vibrating or heating plate will reduce low back pain and increase oxygen saturation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/03/2015, Ludwig-Maximilians-University Munich Ethics Committee (Pettenkoferstr. 8a, Munich, 80336, Germany; +49 (0)89 4400 55191; ethikkommission@med.uni-muenchen.de), ref: 472-14

Study design
Monocenter interventional open-label randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Decreasing low back pain in healthy adults

Interventions
The treatment was carried out on a Spintrac couch from the manufacturer Kurperle GmbH, Bad Füssing. The treatment time was 10 minutes. The therapy was carried out according to the manufacturer's operating instructions. Participants will be randomly assigned to either an infrared/heat group (heat group), a vibration group (VIB group) or a combination group (COMBI group) using a simple randomisation method. In the infrared/heat group, the therapy is carried out using only the heat generated under infrared light (near-infrared range) with a wavelength of 780-1000 nm. In the vibration group, the therapy takes place only by means of vibration (clockwise rotating horizontal oscillation with a frequency of 20 Hz and an oscillation of 1 cm). In the combination group, the therapy is carried out in a combination of the previously described

intervention using infrared light and the previously described clockwise horizontal vibration. Blinding was not possible, so this is an open-label intervention.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Spintrac couch

Primary outcome(s)
Pain measured using a visual analogue scale (VAS) at baseline, post-intervention, and 24h post-intervention

Key secondary outcome(s))
1. Blood oxygen saturation measured using a pulse oximeter at baseline and post-intervention
2. Blood perfusion index measured using a pulse oximeter at baseline and post-intervention

Completion date
01/03/2016

Eligibility

Key inclusion criteria
1. People between the ages of 18 and 80 years old
2. Non-specific back pain in the last 24 hours determined using the VAS scale
3. Greater than 30 mm and less than 90 mm (pain at rest and/or on movement) on the VAS scale at randomization
4. Written informed consent dated and signed by the patient

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
60

Key exclusion criteria
1. Specific back pain
2. Acute inflammatory disease

Date of first enrolment
20/07/2015

Date of final enrolment
29/02/2016

Locations

Countries of recruitment
Germany

Study participating centre
Dr. Hartard Physio Vibbing
Helene-Mayer-Ring 14 ee
Munich
Germany
80809

Sponsor information

Organisation
Kurperle GmbH

Funder(s)

Funder type
Industry

Funder Name
Kurperle GmbH

Results and Publications

Individual participant data (IPD) sharing plan
The datasets analysed during the current study are available upon request from Dr Manfred Hartard, m.hartard@cdg-muenchen.de.
• The type of data that will be shared: Raw study data
• Timing for availability: Upon request
• Whether consent from participants was required and obtained: All ICFs were required and

obtained
• Comments on data anonymization: Patients are only identifiable by their patient ID within the study
• Any ethical or legal restrictions: No

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/06/2025	06/03/2026	Yes	No