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Use of heart rate variability biofeedback to predict and improve pain expectations and experiences in patients with chronic low back pain

Submission date
25/09/2024

Recruitment status
Recruiting

Registration date
25/11/2024

Overall study status
Ongoing

Last Edited
21/05/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This research project aims to investigate the role of autonomic imbalances associated with chronic non-specific back pain, measured by heart rate variability (HRV). The study will measure HRV in patients with persistent back pain both at home and in a clinical setting. The hypothesis is that these measurements are related to both the expectation and intensity of back pain. Additionally, half of the patients will receive a biofeedback application to improve their HRV.

Who can participate?
Anyone who is at least 18 years old and has been suffering from back pain for at least 12 weeks can participate in the study.

What does the study involve?
Participants will have a total of 5 clinic visits and will receive a smartwatch to wear throughout the study, including during sleep. The smartwatches will continuously record HRV data and information on sleep duration and quality. All participants will receive feedback on their measurements and strategies for improvement. Half of the participants will also receive HRV biofeedback training, a non-invasive method to improve HRV. Participants will receive financial compensation for their involvement.

What are the possible benefits and risks of participating?
Benefits: Participants will gain insights into their HRV and sleep patterns, receive strategies for improvement, and financial compensation.
Risks: No serious risks are expected for participants.

Where is the study run from?
The study is conducted at the University Medical Centre Hamburg-Eppendorf in the Department of Psychosomatic Medicine.

When is the study starting and how long is it expected to run for?
April 2024 to September 2027

Who is funding the study?
The study is funded by the ‘Stiftung Psychosomatik der Wirbelsäulenerkrankungen’.

Who is the main contact?
Dr. Paul Hüsing, p.huesing@uke.de

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
1041/128

Study information

Scientific Title
Autonomic imbalance as a predictor of pain expectations and experience in chronic low back pain: a pilot study on the application of heart rate variability biofeedback in a mixed-methods design

Acronym
BACK.BEAT

Study objectives
1. In patients with chronic back pain, the daily average deviations from the baseline heart rate variability correlate at least moderately and negatively ($r \geq -0.5$) with pain expectations and subjective pain intensity.

2. The practicability of an HRV biofeedback manual in patients with chronic back pain to increase HRV and improve the pain experience will be evaluated. Due to the pilot study design, an explorative analysis including a descriptive description of the possible differences between the intervention and control group concerning changes in HRV and pain intensity is carried out.

3. A qualitative process analysis will examine whether the patients' individual disorder model changes in the intervention group. It is assumed that psychosocial factors become more important after the application, while HRV itself is accepted as a biological marker.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 19/03/2025, Local psychological ethics committee (LPEK) at the Centre for Psychosocial Medicine at the University Medical Clinical Hamburg-Eppendorf (Martinistraße 52, Hamburg, 20246, Germany; +49 (0)40741053543; back.beat@uke.de), ref: Reference number not provided

Study design
Single-Centre interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Diagnostic, Treatment

Health condition(s) or problem(s) studied
Chronic back pain

Interventions
All included study participants wear a study smartwatch that records their heart rate variability (HRV) and other health parameters (sleep quality, number of steps, heart rate) continuously for 24 hours for 5 weeks from the baseline. The measurements are blinded; the participants do not receive any feedback on their measured health data. In addition, the study participants indicate their expected pain intensity in the morning and their subjectively experienced pain throughout the day in the evening (survey via smartphone app). All patients are called to the University Medical Center Hamburg-Eppendorf for a total of four ECG measurements with a biofeedback device. The study participants in the intervention condition will receive a total of four sessions of HRV biofeedback as part of the HRV measurements. The sessions have a duration of 45 to 60 minutes, in which the participants are shown their HRV and learn how to directly influence it and which potential stressors can negatively influence it.

Intervention Type
Behavioural

Primary outcome(s)
Heart rate variability measured using the standard deviation of all NN intervals (SDNN), the root mean square of successive differences between normal heartbeats (RMSSD), the natural logarithm of high frequency (lnHF) and the natural logarithm of low frequency (lnLF) at baseline, two-week follow-up (T1), three-week follow-up (T2), four-week follow-up (T3), and five-week follow-up (T4)

Key secondary outcome(s))
1. Pain expectancy measured using a numeric rating scale (0-10) daily in the morning for 5 weeks
2. Pain intensity measured using a numeric rating scale (0-10) daily in the evening for 5 weeks
3. Conceptualization of symptoms measured using the Bodily Symptoms Concepts Questionnaire post-study follow-up (one week after T4)

Completion date
30/09/2027

Eligibility

Key inclusion criteria
1. Minimum age of 18 years old
2. Back pain that has persisted for at least 12 weeks
3. Suffering due to back pain, operationalized by an SSD-12 sum score ≥ 15 and a mean sum score of the visual analogue scales recommended by EURONET-SOMA on pain intensity and limitations ≥5
4. Provision of written informed consent to participate

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Insufficient knowledge of German
2. Acute need for treatment due to other comorbid mental disorders (inpatient treatment required)
2. Severe acute somatic back injury or a known cardiovascular (e.g. pacemaker) or pulmonary disease (e.g. COPD)
3. Presence of acute danger to oneself or others

Date of first enrolment

01/05/2025

Date of final enrolment
01/08/2026

Locations

Countries of recruitment
Germany

Study participating centre
University Medical Clinic Hamburg-Eppendorf, Department of Psychosomatic Medicine and Psychotherapy
Martinistraße 52
Hamburg
Germany
20251

Sponsor information

Organisation
Foundation for Psychosomatics of Spinal Diseases (Stiftung Psychosomatik der Wirbelsäulenerkrankungen)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Universitätsklinikum Hamburg-Eppendorf

Alternative Name(s)
University Medical Center Hamburg-Eppendorf, UKE

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location

Germany

Funder Name
Foundation for Psychosomatics of Spinal Diseases (Stiftung Psychosomatik der Wirbelsäulenerkrankungen)

Results and Publications

Individual participant data (IPD) sharing plan
The dataset generated and/or analysed during the current study will be made available upon reasonable request from Dr. Paul Hüsing, p.huesing@uke.de. Anonymized datasets used for data analysis will be shared after the publication of study results and if consent was provided by participants during recruitment.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes