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Balance training through perceptual training

Submission date
16/10/2023

Recruitment status
Recruiting

[X] Prospectively registered

[_] Protocol

Registration date
24/10/2023

Overall study status
Ongoing

[_] Statistical analysis plan

[_] Results

Last Edited
06/03/2025

Condition category
Ear, Nose and Throat

[_] Individual participant data

[X] Record updated in last year

Plain English summary of protocol

Background and study aims
As people get older, their ability to maintain balance tends to decline, especially after reaching the age of 65. This makes them more prone to falling, and it's not uncommon for many seniors to experience at least one fall in a year.

In our research, we are working to reduce the risk of falls among older individuals by using a special motion device that stimulates the part of the inner ear responsible for balance, called the vestibular system. Previous studies have demonstrated that it's possible to improve one's sense of balance through this kind of training. Additionally, a study conducted in our department has shown promising results, although it has not been officially published yet.

Who can participate?
We will recruit 90 healthy volunteers from the age of 65 and above.

What does the study involve?
The experiment will take 12 days in which the participants will undergo several tests. On the first day, we assess rs-fMRI, VestEP, gait, posture, and vestibular perpetual threshold. From day 2 to day 9 the participants will be divided into 3 groups. One group will be trained on a motion device (perceptual training), one group will be trained by a personal trainer in Tai Chi (exercise), and the last group will receive no training (control). All participants will be tested again on day 10, day 40, and 90 (day 40 and 90 are follow-ups).

What are the possible benefits and risks of participating?
Participants have no risks in this study nor any real benefits. We hope to develop a treatment with which we could train senior citizens vestibular threshold and thereby increase their sense of balance. This would reduce the dangers of falling and could be applied to patients that are temporarily immobilized or in rehabilitation.

Where is the study run from?
University of Bern (Switzerland)

When is the study starting and how long is it expected to run for?
October 2023 to May 2026

Who is funding the study?
University of Bern (Switzerland)

Who is the main contact?
Dr Matthias Ertl
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PL2

Study information

Scientific Title
Vestibular perceptual training in healthy people

Acronym
VPT

Study objectives

We expect to see improvements in the vestibular perceptual thresholds. An improvement is defined as a smaller threshold in the post compared to the pre-training measurement. The groups with vestibular perceptual training (TVPT) and physical activity training (TPA) are expected to show a decrease in vestibular perceptual thresholds (improvement) when comparing participants within subject and when comparing training groups to controls (Tno).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/12/2023, Swissethics, Schweizerische Vereinigung der Forschungsethikkommissionen (Haus der Akademien, Laupenstrasse 7, Bern, CH-3000, Switzerland; +41 31 306 93 95; info@swissethics.ch), ref: 2023-01586

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Laboratory

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Vestibular threshold degregation

Interventions
We will compare individual pre- and post-training performance, as well as group pre- and post-training performance. There will be 3 groups: vestibular stimulation training, Tai Chi training, and no training. There won't be any blinding, as it is not possible. Participants will be tested and trained during 10 days and will be tested again on days 40 and 90.

Group 1 will receive a vestibular perceptual threshold training. During this training the participant will be seated on a motion device while blinded and muted to external sounds. The motion device will then move in a roll or tilt motion to either the right or the left and the participants task will be to guess in which direction they were moved. This will take 1h.
Group 2 will receive 1h Tai Chi training from a personal instructor.
Group 3 will receive no training whatsoever and will only be tested on day 1 and 10

Intervention Type

Behavioural

Primary outcome measure

1. For the vestibular perceptual threshold (VPT) we measure whether the participants can feel in which direction they have been moved (threshold) to either the left or right using a motion device on day 1 (baseline), day 10 (post training), day 40 (follow-up 1), and day 90 (follow-up 2).
2. For the VestEPs we measure the ERP amplitudes (P1, N1. P2) on day 1 (baseline), day 10 (post training), day 40 (follow-up 1), and day 90 (follow-up 2).
3. With the rs-fMRI we measure Connectivity within the cortical vestibular network (OP2, Csv), Connectivity between the vestibular (OP2) and motor system (M1), and cortical thickness on day 1 (baseline), day 10 (post training), day 40 (follow-up 1), and day 90 (follow-up 2).
4. For gait and posture, we measure the acceleration signals on day 1 (baseline), day 10 (post training), day 40 (follow-up 1), and day 90 (follow-up 2).

Secondary outcome measures

1. For the VPT we measure the response times on day 1 (baseline), day 10 (post training), day 40 (follow-up 1), and day 90 (follow-up 2).
2. For the VestEPs we measure the latencies of the ERP amplitudes, time-frequency decomposition analysis of the ERPs, source localization of the ERPs, and a dynamic causal model (DCM) describing the within network alterations over time on day 1 (baseline), day 10 (post training), day 40 (follow-up 1), and day 90 (follow-up 2).
3. For the rs-fMIR we measure volumetric changes on day 1 (baseline), day 10 (post training), day 40 (follow-up 1), and day 90 (follow-up 2).
4. For gait we measure walking duration for the predefined distance on day 1 (baseline), day 10 (post training), day 40 (follow-up 1), and day 90 (follow-up 2).
5. For posture we measure on the stair-condition if participants make use of the hand grip on day 1 (baseline), day 10 (post training), day 40 (follow-up 1), and day 90 (follow-up 2).

Overall study start date
16/10/2023

Completion date
01/05/2026

Eligibility

Key inclusion criteria
Healthy participants from the age of 65 with no neurological diagnosis or physical disabilities within the Bern region will be recruited for this study.

Participant type(s)
Healthy volunteer

Age group
Senior

Lower age limit
65 Years

Upper age limit

135 Years

Sex
Both

Target number of participants
90

Key exclusion criteria
1. Neurologic signs indicative of vertigo due to a central lesion
2. Patients with additional severe cardio-vascular, metabolic, neurological, or degenerative diseases
3. Ear/Vestibular diseases or disorders
4. Intake of neuroleptics or other medication with potential effects on cognition or cause nausea
5. Pregnancy
6. Persons with a pacemaker or other metal in the body which could interfere with the scanner.
7. Implantable Cardioverter Defibrillator
8. Hearing loss
9. Cochlea implant
10. Epilepsy

Date of first enrolment
16/02/2024

Date of final enrolment
01/02/2026

Locations

Countries of recruitment
Switzerland

Study participating centre
Universität Bern
Fabrikstrasse 8
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Sponsor information

Organisation
University of Bern

Sponsor details

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Sponsor type
University/education

Website
https://www.unibe.ch/index_ger.html

ROR
https://ror.org/02k7v4d05

Funder(s)

Funder type
University/education

Funder Name
University of Bern

Alternative Name(s)
Universität Bern, Université de Berne, Universitas Bernensis, UniBE, , Бернскі ўніверсітэт, Бернски университет, Universitat de Berna, Bernská univerzita, Πανεπιστήμιο της Βέρνης, Universitato de Berno, Universidad de Berna, Berni Ülikool, Bernako Unibertsitatea, , Bernin yliopisto, Univèrsitât de Bèrna, Universidade de Berna, , Università di Berna, , Берн університеті, , Berno universitetas, Universiteit van Bern, Universitetet i Bern, Бернский университет, Bern Üniversitesi, Берн университеты, Бернський університет, , UB

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Switzerland

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/01/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon request from https://osf.io/jn2yp/

Data requests can be submitted starting 9 months after article publication and the data will be made accessible for up to 24 months. Extensions will be considered on a case-by-case basis.

Access to trial IPD can be requested by qualified researchers engaging in independent scientific research, and will be provided following review and approval of a research proposal and Statistical Analysis Plan (SAP) and execution of a Data Sharing Agreement (DSA).

IPD sharing plan summary
Stored in publicly available repository, Stored in non-publicly available repository