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Balance training through perceptual training

Submission date	Recruitment status	[X] Prospectively registered
16/10/2023	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/10/2023	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
06/03/2025	Ear, Nose and Throat	[_] 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

Protocol serial number
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

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Prevention

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(s)
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).

Key secondary outcome(s)
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).

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

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 Years

Upper age limit
135 Years

Sex
All

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

ROR
https://ror.org/02k7v4d05

Funder(s)

Funder type
University/education

Funder Name
University of Bern

Alternative Name(s)
UniBE, Universität Bern, Université de Berne, Universitas Bernensis, , UB

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location

Switzerland

Results and Publications

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