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Can mountain hiking and bathing in healing waters improve balance and immune system function in older people?

Submission date
29/10/2018

Recruitment status
No longer recruiting

Registration date
21/11/2018

Overall study status
Completed

Last Edited
21/06/2019

Condition category
Other

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

Plain English summary of protocol

Background and study aims
The average age of world's population is increasing, because life expectancy is rising and birth rate is decreasing. Aging is associated with a loss of immune strength, higher rates of long-term inflammatory diseases and a higher risk for falls. This means that healthcare systems are under increasing pressure. Therefore, aging in good health should be a major goal of public health. Regular physical activity can slow the progression of long-term diseases and improves mobility and balance in the elderly. Mountain hiking is a very popular leisure activity in elderly people, but we know little about the health effects. In this study we investigated the effects of mountain hiking in combination with bathing in thermal healing waters on the immune strength and balance of elderly people.

Who can participate
Community-dwelling men and women aged between 65 and 85 years with at least one typical age-associated disease (e.g. high blood pressure (hypertension), type 2 diabetes, osteoporosis) participated in this study. The participants had to be physically able to perform guided moderate mountain hiking tours lasting 2 to 5 hours.

What does the study involve?
We allocated the participants randomly into two groups: a control group and an intervention group. All participants spent a 7-day holiday either at Bad Wiessee (Germany), Bad Reichenhall (Germany) or Abtenau (Austria). People from the intervention group participated in a mountain hiking and bathing program. The control group at the same time went on a classic sightseeing vacation. We performed medical examinations (balance test, blood tests etc.) at the beginning of the study, after the 7-day holiday, after 2 months and after 6 months.

What are the possible benefits and risks of participating?
The direct benefit for the participants is a 7-day holiday with hiking and bathing or a sightseeing vacation. Moderate mountain hiking is a safe leisure activity. A vacation improves mood and quality of life. There are no specific risk factors for the participants.

Where is the study run from?
The study was run by the Paracelsus Medical University Salzburg. All medical examinations took place at the Paracelsus Medical University Salzburg

When is the study starting and how long is it expected to run for?
October 2015 to December 2016

Who is funding the study?
This research was funded by EU-Interreg Austria-Bavaria 2014-2020; project code AB40.

Who is the main contact?
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Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Balneotherapy and Exercise for the Revitalization of a Geriatric population (BERG)

Acronym
BERG

Study objectives
1. Balneotherapy in combination with mountain hiking improves the dynamic and static balance of people aged 65-85.
2. Balneotherapy in combination with mountain hiking stimulates the immune system and leads to the development of naive T-cells.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Salzburg, 27/01/2016, E1987/5-2016

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Balance, immune system health

Interventions
The intervention group spent a seven-day holiday either in Bad Reichenhall (DE), Bad Wiessee (DE) or Abtenau (AT). The exercise program for the intervention groups was identical in all three regions and was composed of four 3-5-h guided mountain hiking tours with an average altitude difference of 250 m and 10 km in distance per day. The participants of Bad Wiessee bathed three times in Iodine-Sulfur-Na-Cl- water. The intervention group of Abtenau received five baths in highly mineralized Na-Ca-Cl-SO4- water. The intervention group of Bad Reichenhall received five sole (saltwater) baths.
The control group spent at the same time a classical seven-day holiday with sightseeing. Hiking activities, physical training and bathing in the local wellness and balneotherapy facilities was not allowed for the control group.
Randomization was performed using an open-source add-in (Daniel's XL Toolbox, Ver. 7.2.7) for the Microsoft Excel® spreadsheet software, with gender, age and sample size as allocation criteria. The Kullback-Leibler Divergence method was used to ensure that the four groups were as similar as possible.

Intervention Type
Mixed

Primary outcome(s)
1. Static balance assessed using the MFT-S3 Check device (Bodywork, Trend Sport Trading GmbH, Großhöflein, Austria)
2. Dynamic Balance assessed using the Zebris FDM semiautomatic gait analysis mat (Zebris Medical GmbH, Germany)

3. Phagocytosis activity of monocytes and granulocytes assessed using Phagotest (BD Biosciences)
4. Senescent T-cells assessed using 9-color FACS analysis for markers CD3, CD4, CD8, CD57, KLRG1, CD27, CD28, CD45-RA and CCR7
All primary outcomes were assessed at T0-T3 (T0 = Day 0, T1 = Day 7, T2 = Day 60, T3 = Day 180).

Key secondary outcome(s))
1. Body composition assessed using bioelectrical impedance analysis
2. Confidence in balance assessed using Activities-specific Balance Confidence (ABC) Scale questionnaire
3. Depression assessed using the Geriatric Depression Scale questionnaire
4. Wellbeing assessed using WHO-5 questionnaire
5. Dementia assessed using the Digit Symbol Substitution Test
6. White blood cell proportions assessed using a differential blood count
7. Hand grip measured with a digital hand grip dynamometer
8. Physical activity assessed using the German PAQ-50+ questionnaire
All secondary outcomes were assessed at T0-T3 (T0 = Day 0, T1 = Day 7, T2 = Day 60, T3 = Day 180) except PAQ-50+ Questionnaire, which was assessed at T0, T2 and T3.

Completion date
04/12/2016

Eligibility

Key inclusion criteria
1. Aged 65-85 years
2. Community-dwelling
3. Stable chronic age-associated non-immunological condition
4. Normal range of reference laboratory test results
5. Sufficient physical ability to meet the demands of the exercise program.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
139

Key exclusion criteria
1. Cognitive impairment (Folstein Mini Mental State <23)
2. Depression (Geriatric Depression Scale ≥6)
3. Poorly controlled hypertension (systolic blood pressure ≥180 mmHg)

4. Renal insufficiency (serum creatinine ≥2.0 mg/dl)
5. Elevated glucose (non-fasting >200 mg/dl)
6. Malnutrition (serum albumin <3.2 g/l)
7. Lymphocytopenia (total lymphocyte count <1500/microl)
8. Anemia (hematocrit <30%)
9. Abnormal thyroid-stimulating hormone (TSH) levels (<0.3 or >4.0 mU/l)
10. Immunologically mediated chronic conditions
11. Immunodeficiency
12. Severe respiratory disorders
13. Psychiatric disorders
14. Arteriosclerotic event during 2 weeks before enrollment
15. Cardiac insufficiency
16. Malignancies and lymphoproliferative disorders
17. History of alcoholism
18. Current drug abuse
19. Currently smoking >10 cigarettes/day
20. Contraindications for balneotherapy

Date of first enrolment
01/02/2016

Date of final enrolment
01/04/2016

Locations

Countries of recruitment
Austria

Germany

Study participating centre
Paracelsus Medical University Salzburg
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Sponsor information

Organisation
Paracelsus Medical University Salzburg

ROR

https://ror.org/03z3mg085

Funder(s)

Funder type
Government

Funder Name
EU-Interreg Österreich-Bayern 2014-2020 Project

Results and Publications

Individual participant data (IPD) sharing plan
The dataset will be available upon request, after the publication process is finished. Data for gait and balance parameters will be available in 2019. For the remaining data the publication schedule is unknown at this time. Data will be shared with the scientific community (universities) for meta-analyses. Data will be submitted anonymized with a four-digit ID in digital format. Consent from participants was obtained. Data will be only shared for research purposes, not for commercial purposes.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/07/2019	21/06/2019	Yes	No
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