

# Mountain hiking versus nature connection therapy based in Algund as climate therapy for couples

<b>Submission date</b> 17/01/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 26/02/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/03/2023	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

#### The ANKER-Study

In this randomized controlled clinical study, we investigated the effects of moderate mountain hiking and forest therapy on overweight couples with a sedentary lifestyle. The ANKER-Study will investigate possible effects on quality of life, quality of relationship, cardiorespiratory fitness, body composition, inflammation and balance.

### Who can participate?

Overweight couples each aged between 50 and 65 years with a BMI of 25 to 30 and a sedentary lifestyle can participate in the ANKER-Study. Physical fitness for moderate mountain hiking tours is required.

### What does the study involve?

Participants are allocated as couples by random into two groups: a nature-connection group and a hiking-group. Both intervention groups spend a 7-day holiday in Algund, Italy. The nature-connection group participates in five guided forest-therapy sessions and the hiking group undertakes in the meantime five guided mountain hiking tours. Medical examinations will be scheduled at the beginning of the 7 day holiday and at the end of the holiday in Algund, Italy. After 2 months a follow-up examination takes place in Salzburg, Austria. After 6 months, all participants will receive an online questionnaire. The medical examinations include a fitness test, measurement of body composition, questionnaires, differential blood count and measurement of skin parameters. All medical examinations will be performed by members of the Institute of Ecomedicine from the Paracelsus Medical University of Salzburg.

### What are the possible benefits and risks of participating?

All study participants receive a 7-day holiday. A vacation improves mood and quality of life. As a negative side effect of physical activity, exercise-induced bronchoconstriction may occur.

### Where is the study run from?

The Paracelsus Medical University of Salzburg (Austria)

When is the study starting and how long is it expected to run for?  
October 2018 to November 2021

Who is funding the study?  
The Tourism Association of Algund (Italy)

Who is the main contact?  
Dr. Arnulf Hartl  
Paracelsus Medical University Salzburg  
Institute of Ecomedicine  
Strubergasse 21  
5020 Salzburg, Austria

**Study website**  
<https://www.klimatherapie.eu/>

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
18-2019

## Study information

**Scientific Title**

Algender Nature and Climate therapy: green Exercise vs. natuRe connection - The ANKER-Study

**Acronym**

ANKER

**Study objectives**

What are the possible effects of two different types of climate therapy for overweight couples? Do mountain hiking and forest therapy induce different physiological and psychological responses and how sustainable are these effects?

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 13/03/2019, Ethics Committee of Bozen (Comprensorio Sanitario di Bolzano, Via Lorenz Böhler 5 39100 Bolzano; +39 0471908232; comitatoetico.bz@sabes.it), ref: 18-2019

**Study design**

Randomized controlled trial with two intervention groups

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Community

**Study type(s)**

Prevention

**Participant information sheet**

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

**Health condition(s) or problem(s) studied**

Couples who are overweight with a sedentary lifestyle

**Interventions**

Participants are randomized into one of two intervention groups:

The hiking intervention involves five guided hiking tours with an altitude difference ranging from 300 – 700m in altitude.

The nature-connection intervention involves five guided forest-therapy sessions. Each session was guided by a psychologist (<https://www.frontierwellbeing.eu/?lang=de>) and lasted for 3-4 hours. The forest-therapy sessions included elements focusing on relationship, wellbeing and quality of relationship.

Randomization is performed by an open-source add-in (Daniel's XL Toolbox, Ver. 7.2.7) for the Microsoft Excel spreadsheet software, with age, nature relatedness, BMI and activity level as allocation criteria. As allocation method Kullback-228 Leibler Divergence method was used.

Intervention duration for both groups is 7 days based in Algund. Examinations at baseline and 7 days take place at the Hospital of Meran. Examinations include a fitness test, measurement of body composition, questionnaires, differential blood count and measurement of skin parameters. One follow up takes place at 60 days at the Paracelsus Medical University Salzburg where the above examinations are repeated. A second follow up is scheduled at day 180 involving only an online questionnaire.

## **Intervention Type**

Mixed

## **Primary outcome measure**

1. Health-related quality of life is measured using short form 12 health survey (SF12) and EuroQol (EQ-5D) health status questionnaire at baseline, 7, 60 and 180 days
2. Quality of relationship is measured using relationship questionnaire (Partnerschaftsfragebogen; PFB) and problem list (Problemliste; PL) at baseline, 7, 60 and 180 days

## **Secondary outcome measures**

1. Body composition is measured using bio-impedance analysis (BIA) at baseline, 7 and 60 days
2. Cardiorespiratory fitness is measured using the Chester Step Test at baseline, 7 and 60 days
3. Balance is measured using the body stability check (MFT-S3) at baseline, 7 and 60 days
4. Inflammation is measured using differential blood count and cytokine profile from serum or plasma at baseline, 7 and 60 days
5. Airway inflammation is measured using an exhaled nitric oxide (FeNO) test at baseline, 7 and 60 days
6. Skin quality is measured by transepithelial water loss at baseline, 7 and 60 days
7. Nature connection is measured using the Nature relatedness scale (NRS), Flourishing Scale (FS-D), Connectedness to nature scale (CNS) at baseline, 7, 60 and 180 days
8. Quality of life measured using the Satisfaction with Life Scale (SWLS) and Beschwerdeliste at baseline, 7, 60 and 180 days
9. Mindfulness is measured using the Mindful attention awareness scale (MAAS) and health-related control belief questionnaire (GKÜ) at baseline, 7, 60 and 180 days

## **Overall study start date**

01/10/2018

## **Completion date**

01/11/2021

# **Eligibility**

## **Key inclusion criteria**

1. Couples both aged from 50 to 65 years
2. Couples both with BMI between 25 and 30
3. Sedentary Lifestyle, International Physical Activity Questionnaire (IPAQ) score of <3.000 MET

mins/week

4. Ability to participate in physical exercise (moderate intensive mountain hiking) as determined by the investigator

**Participant type(s)**

Healthy volunteer

**Age group**

Adult

**Sex**

Both

**Target number of participants**

120 participants, 60 couples

**Key exclusion criteria**

1. Immunologically mediated chronic conditions or immunodeficiency
2. Severe respiratory disorders
3. Acute or untreated psychiatric disorders
4. Uncontrolled hypertension
5. Uncontrolled metabolic diseases
6. Acute infection or fever
7. Diagnosis of or treatment for malignant neoplastic disorders within the last 5 years
8. Arteriosclerotic event <6 months before enrollment
9. Cardiac insufficiency
10. Renal insufficiency
11. Diagnosis or history of alcoholism
12. Current recreational drug use
13. Currently smoking >10 cigarettes/day
14. Orthopedic contraindications for hiking
15. Medication intake >5mg/d Prednisone, Colchicine, Imuran, Methotrexate, Azathioprine, Cyclophosphamide or Cyclosporine
16. Intake of weight-loss drugs or preparations
17. Pregnancy

**Date of first enrolment**

25/03/2019

**Date of final enrolment**

24/02/2020

**Locations**

**Countries of recruitment**

Austria

Germany

Italy

**Study participating centre**  
**Paracelsus Medical University Salzburg**  
Institute of Ecomedicine  
Strubergasse 22  
Salzburg  
Austria  
5020

**Study participating centre**  
**Tappeiner Hospital Merano**  
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## **Sponsor information**

**Organisation**  
Paracelsus Medical University

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**Sponsor type**  
University/education

**Website**  
<https://www.pmu.ac.at/>

**ROR**  
<https://ror.org/03z3mg085>

## **Funder(s)**

**Funder type**

Government

## Funder Name

Tourism Association Algund

## Results and Publications

### Publication and dissemination plan

Planned publication in a peer-reviewed journal

### Intention to publish date

01/03/2022

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. Arnulf Hartl, Paracelsus Medical University Salzburg, Institute of Ecomedicine, Strubergasse 22, 5020 Salzburg, Austria

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		24/03/2022	28/03/2023	Yes	No
<a href="#">Results article</a>		13/01/2023	28/03/2023	Yes	No