

# Hiking and Coaching (HICO): Lifestyle change for prevention of diseases

<b>Submission date</b> 14/05/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 18/11/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/01/2023	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The HICO-Study aims to investigate whether a physically active stay (mountain hiking) in the Alpine region with or without psychological coaching has a lasting impact on cardiorespiratory fitness, lifestyle, physiological and psychological stress, quality of life and clinical measurements of metabolism.

### Who can participate?

The study includes subjects between the ages of 22 and 54 who have a sedentary lifestyle.

### What does the study involve?

The study is carried out as part of a 7-day vacation in 4 regions in Salzburg Land.

Participants are randomly allocated to one of three groups. The participants in groups 1 and 2 complete a structured exercise program of mountain hiking from Sunday to Friday (no hiking on Wednesdays) with a daily height difference of at least 600 meters. The participants in group 1 additionally receive 3 individual psychological coaching units during the exercise program week and one at the follow-up visit around 80 days after the vacation. The participants in the third group have no exercise program or coaching.

All three groups are given the same questionnaires and examinations are collected over the study period. All medical examinations are performed by members of Institute of Ecomedicine respectively of the Institut für Physiologie und Pathophysiologie 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 often improves mood and quality of life. The findings from the study may be that taking part in an exercise program and psychological coaching can cause an increase in cardiorespiratory fitness and quality of life and that these effects are sustainable. As a negative side effect of physical activity, exercise-induced muscular discomfort 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?  
From January 2012 to February 2013

Who is funding the study?  
The European Fund for Regional Development (EU) and the participating hotel companies in Pinzgau.

Who is the main contact?  
Dr. Arnulf Hartl  
arnulf.hartl@pmu.ac.at

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
415-E/1488/2-2012

## Study information

**Scientific Title**  
The HICO study: Sustainability of a multimodal intervention on health awareness and quality of life of 30-50 year old healthy adults with special attention to exercise. A randomized controlled trial

**Acronym**  
HICO

## **Study objectives**

1. Mountain hiking +/- psychological coaching has a lasting positive influence on the cardiorespiratory fitness of healthy subjects with a sedentary lifestyle
2. Improvement in quality of life, psychological health and quality of the relationships of couples, reduction of stress, and positive effect of coaching

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 04/05/2012, the Ethics Committee for the State of Salzburg (Stefan-Stief-Gasse 2, Postfach 527, 5010 Salzburg Austria; ethikkommission@salzburg.gv.at; +43 662 8042 0), ref: 415-E/1488/2-2012

## **Study design**

Three-arm randomized controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Prevention

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

Sedentary lifestyle

## **Interventions**

Participants are invited as couples and are allocated to the same intervention group, they will then be treated as a single participant. Participants are randomized into one of three intervention groups:

1. 1st arm is an intervention group which involves mountain hiking and psychological coaching
2. 2nd arm is an intervention group which involves mountain hiking
3. 3rd arm is the control group who receive no treatment

Randomization is carried out using the "Random Allocation Software" program with a block randomization protocol (Saghaei 2004). Due to a shortage of suitable patients, only the hiking and the coaching groups are randomized.

The study is carried out as part of a 7-day vacation in 4 different regions in Salzburg Land. All subjects in both intervention groups complete a structured exercise program of mountain hiking with a daily height difference of at least 600 m. The subjects in the coaching group also receive 3 individual psychological coaching units during the intervention week and one at the follow-up visit. The follow-up visit occurs at approximately 80 days after the first intervention. In the control group without treatment, the same questionnaires and examinations are collected over the same period. All medical examinations are performed by members of the Institute of Ecomedicine respectively of the Institut für Physiologie und Pathophysiologie from the Paracelsus Medical University of Salzburg.

## **Intervention Type**

Mixed

## Primary outcome(s)

Cardiorespiratory fitness is measured by Rockport-Test and Spirometry at baseline, 7 and 80 days

## Key secondary outcome(s)

1. Quality of Life measured using the European Quality of Life-5 Dimensions (EQ-5D) survey, 36-Item Short Form Survey (SF-36) and Visual Analogue Scale (VAS) at baseline, 7 and 80 days
2. Stress measured using the Burnout Screening Scales (BOSS I and BOSS II), Stress Coping Style Questionnaire (SVF78), Trier Inventory for Chronic Stress (TICS), Recreation-Stress-Questionnaire (Erholungs-Belastungs-Fragebogen, EBF) and Nexus stress test (Nexus-10 and Nexus-16) at baseline, 7 and 80 days
3. Quality of relationship measured using the Partnership diagnostics questionnaire (Partnerschaftsfragebogen, PFB and Problemliste, PL) at baseline, 7 and 80 days
4. Psychological health state measured using the Positive and Negative Affect Schedule (PANAS), Self-Compassion Scale (SCS12) and General Health Questionnaire (GHQ) at baseline, 7 and 80 days
5. Effect of Coaching measured using the Work-related behavior and experience pattern (Arbeitsbezogenes Verhaltens- und Erlebensmuster, AVEM) and Questionnaire for Self-Management and Resources (Fragebogen zur Erfassung von Ressourcen und Selbstmanagementfähigkeiten, FERUS) at baseline, 7 and 80 days

## Completion date

01/02/2013

## Eligibility

### Key inclusion criteria

Couples where both partners meet the criteria:

1. Aged 22 to 54 years
2. Sedentary lifestyle, defined as a score of  $\leq 1.6$  on the questionnaire from Johansson and Westerterp (2008)

### Participant type(s)

Healthy volunteer

### Healthy volunteers allowed

No

### Age group

Adult

### Sex

All

### Total final enrolment

90

### Key exclusion criteria

1. Malignant neoplastic diseases
2. Cardiovascular diseases and severe hypertension level 3
3. Orthopedic diseases

4. Acute pain
5. Pulmonary dysfunction
6. Uncontrolled metabolic diseases e.g. diabetes mellitus
7. Active infectious diseases
8. Pregnancy
9. Taking antihypertensive medication

**Date of first enrolment**

07/05/2012

**Date of final enrolment**

15/10/2012

## Locations

**Countries of recruitment**

Austria

**Study participating centre**

**Paracelsus Medical University Salzburg**

Institute of Ecomedicine

Strubergasse 21

Salzburg

Austria

5020

## Sponsor information

**Organisation**

Paracelsus Medical University

**ROR**

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

## Funder(s)

**Funder type**

Government

**Funder Name**

European Regional Development Fund

### Alternative Name(s)

Fondo Europeo de Desarrollo Regional, Europäischer Fonds für regionale Entwicklung, Европейски фонд за регионално развитие, Evropský fond pro regionální rozvoj, Fundo Europeu de Desenvolvimento Regional, ERDF, FEDER, EFRE, ЕФРР, EFRR

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

### Funder Name

Participating hotel companies in Pinzgau

## Results and Publications

### 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="#">Results article</a>		24/03/2022	03/01/2023	Yes	No
<a href="#">Basic results</a>		03/06/2020	18/11/2020	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes