

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

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

Study website

<http://gesund-umdenken.com/>

Contact information

Type(s)

Scientific

Contact name

Dr Arnulf Hartl

ORCID ID

<http://orcid.org/0000-0001-9626-6425>

Contact details

Paracelsus Medical University Salzburg

Institute of Ecomedicine

Univ. Doz. Dr. Arnulf Hartl

Strubergasse 22

Salzburg

Austria

5020

+43 (0)662 2420 80530

arnulf.hartl@pmu.ac.at

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

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

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 measure

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

Secondary outcome measures

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

Overall study start date

01/01/2012

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 ≤ 1.6 on the questionnaire from Johansson and Westerterp (2008)

Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Both

Target number of participants

90 participants, 30 persons per group

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

Sponsor details

Research Office
Strubergasse 21
Salzburg
Austria
5020
+43 699 14420095
d.koelblinger@pmu.ac.at

Sponsor type

University/education

Website

<http://www.pmu.ac.at/>

ROR

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

Funder(s)

Funder type

Government

Funder Name

European Regional Development Fund

Alternative Name(s)

Europski Fond za Regionalni Razvoj, Den Europæiske Fond for Regionaludvikling, Europees Fonds voor Regionale Ontwikkeling, Euroopa Regionaalarengu Fond, Fonds Européen de Développement Régional, Europäischer Fonds für regionale Entwicklung, Európai Regionális Fejlesztési Alap, Fondo Europeo di Sviluppo Regionale, Eiropas Reģionālās attīstības fonds, Europos Regionines Pletros Fondas, Europejski Fundusz Rozwoju Regionalnego, Fundo Europeu de Desenvolvimento Regional, Fondul European de Dezvoltare Regională, Európsky Fond Regionálneho Rozvoja, Fondo Europeo de Desarrollo Regional, Европейски фонд за регионално развитие, Evropský fond pro regionální rozvoj, Ευρωπαϊκό Ταμείο Περιφερειακής Ανάπτυξης, Il-Fond Ewropew għall-Iżvilupp Reġjonali, Evropski sklad za regionalni razvoj,

Euroopan aluekehitysräho, Europeiska regionala utvecklingsfonden, ERDF, FEDER, EFRE, EΦPP, EFRR, EFRU, ERFi, ETΠA, FEDER, FESR, ERAF, ERPF, ERFA, L-FEŽR, EFRO, EFRR, FEDR, ESRR, EAKR, Eruf

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Funder Name

Participating hotel companies in Pinzgau

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal.

Intention to publish date

30/09/2020

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?
Basic results		03/06/2020	18/11/2020	No	No
Results article		24/03/2022	03/01/2023	Yes	No