ISRCTN99926592 https://doi.org/10.1186/ISRCTN99926592

Green exercise and bathing therapy for the treatment of non-specific chronic low back pain

Submission date
06/07/2018

Recruitment status
No longer recruiting

Registration date
19/07/2018

Overall study status
Completed

Last Edited
20/05/2019

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Non-specific chronic low back pain (nscLBP) is a highly relevant condition, due to its prevalence and associated costs. Therefore, it is important to look at effective ways to treat nscLBP. Green exercise (exercise in natural environments) and balneotherapy (bathing in thermal mineral springs) are seen as good treatment options, but there have been no scientific trials to determine the effectiveness of these therapies.
This trial aimed to determine whether moderate mountain hiking, a form of green exercise alone or combined with bathing in thermal water (Mg-Ca-SO_4 balneotherapy) is an effective, economic nature therapy to reduce the symptoms and improve the wellbeing of patients with non-specified chronic low back pain.

Who can participate?
Men and women aged 19-65 with diagnosed non-specific chronic low back pain (ncsLBP) who have received repeated medical treatment as a result.

What does the study involve?
Participants are randomly allocated to either the control group or one of two intervention groups – GE (green exercise) or GEBT (green exercise and balneotherapy).
The GE and GEBT groups spend 8 days in the village of Grins (Tyrol, Austria) in comparable hotels and receive the same meals. Participants in both groups receive a medical assessment (day 0) upon arrival on Saturday. On Sunday to Friday, GE and GEBT participants undertake daily guided hiking tours in the mountains (green exercise). On the following Saturday (day 8), participants in both groups receive an identical medical assessment to their arrival and then depart.
Participants in the GEBT group also undertake daily 20 minute baths in thermal water.
Participants receive the same medical assessment again at day 120.
Participants in the control group only receive the same medical assessments as GE and GEBT participants at day 0, day 8 and day 120.

What are the possible benefits and risks of participating?
The possible benefit to participants of taking part is relief from their nscLBP symptoms. However, a possible risk of taking part is that it may aggravate their nscLBP symptoms. Aside from this, there are no known benefits or risks to participants.

Where is the study run from?
Trial study centre: Grins, Tyrol, Austria
Trial run from: Paracelsus Medical University of Salzburg, Strubergasse 22, 5020 Salzburg, Austria

When is the study starting and how long is it expected to run for?
March 2012 to March 2015

Who is funding the study?
EU-Leader Project (regioL, Health and Energy) (Austria)

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

Contact information

Type(s)
Scientific

Contact name
Dr Arnulf Hartl

Contact details
Strubergasse 22
Salzburg
Austria
5020

Additional identifiers

Protocol serial number
415-E/1487/4-2012

Study information

Scientific Title
Green exercise and Mg-Ca-SO4 thermal balneotherapy for the treatment of non-specific chronic low back pain: a randomized controlled clinical trial

Acronym
N/A

Study objectives
This randomised controlled trial was conducted to find out whether green exercise - in this case moderate mountain hiking - combined with Mg-Ca-SO4 thermal balneotherapy is an effective and economic nature therapy to reduce symptoms and improve wellbeing of patients with nscLBP

Ethics approval required

Old ethics approval format

Ethics approval(s)
Ethikkommission für das Bundesland Salzburg, 04/05/2012, 415-E/1487/4-2012

Study design
Interventional three-armed randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Non-specific chronic low back pain (nscLBP)

Interventions
Participants were stratified by the Korff assessment (pain related disability) and then separated into three groups (control and two intervention groups) using Random Allocation Software 2.0 using block randomisation. The two intervention groups were green exercise (GE) and green exercise and balneotherapy (GEBT).
Participants in the GE and GEBT groups spent 8 days at the village of Grins (Tyrol, Austria) in comparable hotels and received the same meals. Participants arrived on Saturday and underwent medical measurements and anamnesis of their medical history (day 0). Medical measurements involved use of the Oswestry Low Back Disability Index, Medical Outcomes Study Short Form 36, Modified Visual Analogue Scale, World Health Organisation Well-Being Index, a pain diary, assessment of medical consultations and days of incapacity to work, along with Spine-Check Score MediMouse®, Back Performance Scale and torso rotation.
From Sunday to Friday, participants undertook guided hiking tours (green exercise) in the mountains. On the following Saturday, all participants underwent identical medical assessment (day 8) to their arrival day, and departed after this was completed. Follow-up examinations were conducted on day 120.
Participants in the GE group participated in green exercise only. Participants in the GEBT group participated in green exercise and also received balneotherapy, where they bathed in Mg-Ca-SO_4 thermal water in the Albenbad every day for 20 minutes.
Participants in the control group underwent no intervention and only underwent the medical measurements and anamnesis listed above at day 0, day 8 and day 120.

Intervention Type
Other

Primary outcome(s)
Functional spine mobility measured using MediMouse (Spine Check Score) at day 0, 8 and 120.

Key secondary outcome(s))
The following were measured at day 0, 8 and 120:
1. Subjective pain assessed using the mVAS
2. Status of health assessed using the mVAS
3. Back performance assessed using parts of the Back Performance Scale (sock test left/right and lift test)

4. Torso/spine rotation measured using digital goniometer
5. Health-related quality of life assessed using SF-36 questionnaire
6. Depression in chronic illness assessed using WHO-5 questionnaire
7. Claim of medical care assessed through querying pain medication, status of illness and number of medical consulations
8. Pain behaviour and activities of daily living for patients with cLBP measured using Oswestry Disability Index

Completion date
01/03/2015

Eligibility

Key inclusion criteria
1. Diagnosed with non-specific low back pain (nscLBP)
2. Aged 19-65 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
80

Key exclusion criteria
1. Previous operations in lumbar spine area
2. Suspected disc herniation
3. Acute pain in low back area
4. Confirmed osteoporosis
5. Hernia
6. Pregnancy
7. Contraindications of balneotherapy, including:
7.1. Cardiovascular dysfunction (e.g. unstable hypertension, angina pectoris, thrombosis, pulmonary dysfunction, endocrine disorders such as hyperthyroidism and hyperparathyroidism)
7.2. Uncontrolled metabolic disorders (e.g. diabetes mellitus)
7.3. Active infectious diseases
7.4. Incontinence

Date of first enrolment
01/03/2013

Date of final enrolment

01/07/2013

Locations

Countries of recruitment
Austria

Germany

Study participating centre
Paracelsus Medical University
Strubergasse 22
Salzburg
Austria
5020

Sponsor information

Organisation
This project was funded by an EU-Leader Project (regioL, Health and Energy).

Funder(s)

Funder type
Not defined

Funder Name
This project was funded by an EU-Leader Project (regioL, Health and Energy).

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 Arnulf Hartl (arnulf.hartl@pmu.ac.at), with individual deidentified participant data available, along with the study protocol and informed consent form. Data will be available from 9 months until 36 months following article publication. Data will be shared with investigators whose proposed use of the data has been approved by an independent review committee (“learned intermediary”) identified for this purpose - it will be available for individual participant data meta-analysis.

, type of data, when the data will become available and for how long, by what access criteria data will be shared including with whom, for what types of analyses, and by what mechanism, whether consent from participants was obtained, comments on data anonymisation, any ethical or legal restrictions, any other comments)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/05/2019	20/05/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes