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The impact of green exercise on male patients with chronic non-specific back pain in a standard rehabilitation program

Submission date
09/07/2024

Recruitment status
No longer recruiting

Registration date
29/07/2025

Overall study status
Completed

Last Edited
29/07/2025

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The study is part of an EU Interreg project that deals with the health effects of forests and water. The aim of the study is to investigate the extent to which green exercise works as part of back rehabilitation compared to standard rehabilitation without green exercise.

Who can participate?
Male patients aged between 18 and 65 years with chronic nonspecific low back pain and sufficient physical fitness to participate in outdoor activities

What does the study involve?
Participants are randomly allocated to one of two groups:
1. Standard rehabilitation with indoor activation
2. Standard rehabilitation with outdoor activation (green exercise and forest therapy)
The duration of the intervention will be 14 days. The standard rehabilitation programme consists of elements of activation (e.g. physiotherapy, back school, gymnastics) and relaxation (e.g. autogenic training). While the activation part for the patients in the first study group is carried out indoors, these rehabilitation elements for the patients in the second group should all take place outdoors and with the help of guided green exercise and forest therapy.
Back-specific parameters are measured at the beginning (T1) and end (T2) of back rehabilitation (standard vs extra green exercise) as well as 90 (T3) and 180 days after the end of rehabilitation (T4).

What are the possible benefits and risks of participating?
Participation may not necessarily result in any additional direct benefit for health. However, the health benefits of standard rehabilitation are not jeopardized by participation, and an improvement in health may be achieved through the therapy carried out. The measures carried out as part of the study are not associated with any increased risk compared to standard rehabilitation.

Where is the study run from?
Bad Hofgastein spa centre (Austria)

When is the study starting and how long is it expected to run for?
January 2023 to December 2025

Who is funding the study?
EU-Interreg project WiWa2 (EU-Interreg Bavaria-Austria, project code BA100027)

Who is the main contact?
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Additional identifiers

Protocol serial number
2024-0002

Study information

Scientific Title

Effective factors of the natural healing resources forest and water - the impact of green exercise on male patients with chronic non-specific back pain in a standard rehabilitation program

Acronym
WiWa2

Study objectives
The rehabilitation success in the intervention group (green exercise and forest therapy) differs from that of the control group with regard to the primary target parameters of indication-related quality of life (Oswestry Low Back Disability Index [ODI]) and mobility of the back (Spine Check) in patients with chronic non-specific low back pain.

The rehabilitation success in the intervention group (green exercise and forest therapy) differs from that of the control group in terms of the secondary target parameters of functional performance (Back Check), static balance (MFT-S3 Check), pain (Visual Analogue Scale for Rest and Movement Pain, Painkiller Consumption) and quality of life.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 19/06/2024, Ethics Committee of Paracelsus Medical University Salzburg (Strubergasse 21, Salzburg, 5020, Austria; +43 (0)662 2420-80356; ethik.kommission@pmu.ac.at), ref: PMU-EK-2024-0002

Study design
Randomized controlled intervention study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic non-specific back pain

Interventions
In this two-arm monocentric study, male patients diagnosed with chronic nonspecific low back pain will be compared in the following intervention arms:
1st arm: standard rehabilitation (treatment as usual TAU) with indoor activation
2nd arm: standard rehabilitation (TAU) with outdoor activation (green exercise and forest therapy)

The researchers will randomize according to the stratified sampling approach. The randomization factors are age, maximum pain and duration of pain (in years).

The duration of the intervention will be 14 days. For both study arms, the therapy standards of the Austrian social insurance organisations for back pain patients will be adhered to. The rehabilitation programme as TAU therefore consists of elements of activation (e.g. physiotherapy, back school, gymnastics) and elements of relaxation (e.g. autogenic training).

While the activation part for the patients in the first study arm is carried out indoors, these rehabilitation elements for the patients in the second study arm should all take place outdoors and with the help of guided green exercise and forest therapy.

Intervention Type
Mixed

Primary outcome(s)
1. Indication-related quality of life measured using the Oswestry Low Back Disability Index (ODI) at the beginning (T1) and end (T2) of back rehabilitation as well as 90 (T3) and 180 days after the end of rehabilitation (T4)
2. Indication-related posture, mobility, postural competence measured using Spine-Check at the beginning (T1) and end (T2) of back rehabilitation

Key secondary outcome(s))
1. Back muscle strength measured using Back Check at the beginning (T1) and end (T2) of back rehabilitation
2. Static balance measured using MFT-S3-Check at the beginning (T1) and end (T2) of back rehabilitation
3. Pain measured using the visual analogue scale for pain at rest and pain on movement and painkiller consumption at the beginning (T1) and end (T2) of back rehabilitation as well as 90 (T3) and 180 days after the end of rehabilitation (T4)
4. Quality of life measured using the Quality of Life Short Form 12 (SF12) at the beginning (T1) and end (T2) of back rehabilitation as well as 90 (T3) and 180 days after the end of rehabilitation (T4)
5. Wellbeing measured using the World Health Organisation- Five Well-Being Index (WHO-5) at the beginning (T1) and end (T2) of back rehabilitation as well as 90 (T3) and 180 days after the end of rehabilitation (T4)
6. Symptoms of depression and anxiety measured using Patient Health Questionnaire-4 (PHQ-4) at the beginning (T1) and end (T2) of back rehabilitation as well as 90 (T3) and 180 days after the end of rehabilitation (T4)
7. Ability to work measured using the Work Ability Index (WAI) measured using Patient Health Questionnaire-4 (PHQ-4) at the beginning (T1) of back rehabilitation as well as 90 (T3) and 180 days after the end of rehabilitation (T4)
8. Pain-related anxiety measured using the Fear-Avoidance-Beliefs-Questionnaire (FABQ) at the beginning (T1) and end (T2) of back rehabilitation as well as 90 (T3) and 180 days after the end of rehabilitation (T4)
9. Physical activity measured using the European Health Interview Survey - Physical Activity Questionnaire (EHIS-PAQ) at the beginning (T1) of back rehabilitation as well as 90 (T3) and 180 days after the end of rehabilitation (T4)

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Aged between 18 and 65 years
2. Male
3. Diagnosed with chronic nonspecific low back pain (ICD M40-M54)

4. Sufficient physical fitness to participate in the outdoor activities (PAR-Q)
5. Sufficient linguistic and cognitive abilities to participate in the study, especially in terms of the ability to understand the consent form, to adequately implement exercise instructions from medical and health science professionals and to answer questionnaires
6. Written declaration of consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
Male

Key exclusion criteria
1. Untreated or acute malignant diseases
2. Previous operations in the lumbar spine area
3. Suspected herniated disc causing the current symptoms and contradicting participation in the study programme
4. Contraindications to balneotherapy: manifest concomitant internal diseases, unstable high blood pressure, thrombosis, endocrine diseases such as hyperthyroidism and hyperparathyroidism, other uncontrolled metabolic diseases such as diabetes mellitus, active infectious diseases, incontinence
5. Hernias
6. History of cerebrovascular and neurological diseases
7. Inflammatory rheumatic diseases (including inflammatory rheumatic diseases of the joints, vessels and connective tissue)
8. Primary and secondary immunodeficiencies that do not allow participation in the activity programme (PAR-Q)
9. Severe respiratory diseases that require oxygen supplementation
10. Acute or untreated mental illness (Beck's Depression Inventory >19)
11. Heart failure that does not allow participation in the activity programme (NYHA stages 3 and 4) (PAR-Q)
12. Renal insufficiency that does not allow participation in the activity programme (PAR-Q)
13. CHD patients who do not allow participation in the activity programme (PAR-Q)
14. Alcohol abuse (ICD F10.1), drug abuse (ICD F11-F19)
15. Intake of >5 mg/d prednisone and all glucocorticoids from a corresponding prednisone equivalent
16. DMARD therapy such as azathioprine, colchicine, cyclophosphamide, ciclosporin, methotrexate or interferon preparations
17. Taking preparations from the Jak inhibitor group (Olumiant, Xeljanz etc) or TNF alpha

inhibitors
18. Infiltration therapy of the lumbar spine <3 months
19. Insufficient knowledge of German (written and spoken/questionnaires)

Date of first enrolment
01/07/2024

Date of final enrolment
30/09/2024

Locations

Countries of recruitment
Austria

Study participating centre
Bad Hofgastein Therapy Centre GmbH & Co. KG
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Sponsor information

Organisation
Paracelsus Medical University

ROR
https://ror.org/03z3mg085

Funder(s)

Funder type
Government

Funder Name
EU Interreg Bavaria-Austria 2021-2027

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 (arnulf.hartl@pmu.ac.at).

IPD sharing plan summary

Available on request