

Rehabilitation treatment in patients with back pain

Submission date 14/12/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/01/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 30/01/2019	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

One of the most common causes of back pain disease is low back pain (LBP). Low back pain creates significant social and economic problems for many people. Approximately 60-80 % of people suffer from low back pain at least once in their life.. Our goal is to test how well works the rehabilitation in the treatment of these patients.

Who can participate

Adults with low back pain, who are patients of our Rehabilitation Institute.

What does the study involve

Our patients stay in our facility for 4-6 weeks. During these weeks they will get this treatment: all patients will receive at least five individual 30-minute rehabilitation exercise per week. They will also undergo twelve 30-minute group exercise sessions per week in a gymnasium and swimming pool. In addition patients will receive other therapies, i.e., electrotherapy, hydrotherapy, and massages.

Before and after the treatment we will measure some values using methods called posturography and plantography. All we need patients to do is to stay unsupported for 30 seconds. We will compare the results before and after treatment.

Patients will be also asked to label the level of the pain on the scale before and after the treatment.

What are the possible benefits and risks

Patients can benefit from this study by experiencing relief from the low back pain, body posture and stability improvement. Others may benefit in the future from the information we find in this study.

We don't expect any direct risk to the patients.

Where is the study run from

Rehabilitation Institut Brandýs nad Orlicí, Czech republic.

When is the study starting and how long is it expected to run
01/01/2017 to 30/06/2018.

Who is funding the study

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Who is the main contact

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Contact information

Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

3/2018

Study information

Scientific Title

Efficacy of Rehabilitation Exercise and Treatment of Patients with Chronic Low Back Pain measured by posturography and plantography before and after the treatment

Study objectives

Evaluation of efficacy of our special rehabilitation treatment (INFINITY Method) measured by posturography and plantography before and after the treatment

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Rehabilitation Institute Brandys nad Orlicí, 01/02/2017

Study design

Interventional, non-randomised

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Chronic low back pain

Interventions

All patients were hospitalized in our Rehabilitation Institute for 4-6 weeks and underwent:

1. At least five individual 30-minute special rehabilitation sessions per week
2. Six 30-minute group exercise sessions per week in a gymnasium and swimming pool

The INFINITY method is a rehabilitation approach based on neurophysiology, biomechanics, and anatomy. This Process encourages adjustment of the postural control system of the body, which gradually improves balance and symmetrization of the whole body in space, thus creating a precondition for better quality and more efficient movement. The rehabilitation is aimed at stabilizing, strengthening, and stretching of the thoracic, back, and abdominal muscles, including deep stabilizing system (DSS) with connection to diaphragmatic breathing. At the same time, the INFINITY method® enables increased mobility and flexibility via relaxation, stretching, mobilization and release of soft tissues of the musculoskeletal system. This rehabilitation approach uses active and passive exercises with supportive therapies including breathing exercises.

There was no participant follow-up.

Intervention Type

Other

Primary outcome measure

Objective posturography will be measured using the following parameters at the baseline and after 4 weeks of treatment:

1. Feet parallel, eyes open (cm)- area before 2.76, area after 2.23
2. Feet parallel, eyes closed (cm)- area before 3.09, area after 2.40

Secondary outcome measures

Subjective pain reduction will be measured using the visual analogue scale (VAS) at baseline and after 4 weeks of treatment.

Overall study start date

01/01/2017

Completion date

30/06/2018

Eligibility

Key inclusion criteria

1. Clinical diagnosis of low back pain
2. Confirmation of degenerative disease of lumbar spine by the MRI
3. The ability to stay unsupported for 30 seconds

Participant type(s)

Patient

Age group

Mixed

Sex

Both

Target number of participants

331

Key exclusion criteria

1. Immobile patients

Date of first enrolment

30/06/2017

Date of final enrolment

31/10/2017

Locations

Countries of recruitment

Czech Republic

Study participating centre

Rehabilitation Institut Brandys nad Orlici

Lazenska 58

Brandys nad Orlici

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Sponsor information

Organisation

Rehabilitation Institut Brandys nad Orlici

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<https://www.rehabilitacniustav.cz/cs>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Rehabilitation Institut Brandys nad Orlici

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

30/06/2019

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date