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Vojta therapy in multiple sclerosis rehabilitation

Submission date
05/02/2022

Recruitment status
No longer recruiting

Registration date
16/02/2022

Overall study status
Completed

Last Edited
16/02/2022

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Multiple sclerosis (MS) is one of the most common causes of neurological disability that affects young adults. It is a lifelong condition that affects the brain and nerves. Gait and balance problems are one of the most common symptoms of the disease even in the early stages, affecting more than 75% of people with MS. These problems affec gait, with a great risk of falling, and also affect most daily life activities, with a great impact on quality of life. Therefore, attention to this problem has to be taken as a priority. The aim of this study will be to compare the short- and long term effects of Vojta therapy and standard rehabilitation on gait, balance, postural control and pain.

Who can participate?
Patients aged 18 years and over with chronic low back pain

What does the study involve?
Participants will be randomly allocated to receive Vojta therapy or standard rehabilitation, 10 times in total. Gait, body balance, muscle pain and postural control will be measured before and after treatment and during follow-up visits 1 and 3 months after the end of the study.

What are the possible benefits and risks of participating?
Participants will receive a complete treatment program, which may lead to improved gait, body balance and postural control and reduced muscle pain. Risks include temporary fatigue up to 24 hours after the first exercise procedures.

Where is the study run from?
1. University of Opole (Poland)
2. Malgorzata Fuchs Fizjoterapia (Opole)

When is the study starting and how long is it expected to run for?
August 2021 to December 2023

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

KB-807/2021

Study information

Scientific Title
Vojta therapy improves gait and postural control in multiple sclerosis rehabilitation

Acronym
VojtaNDT & MS

Study objectives
1. Vojta therapy improves gait parameters in multiple sclerosis (MS) patients compared to standard rehabilitation
2. Vojta stimulation is effective in muscle pain relief in MS
3. The Vojta approach improves body balance, stability and postural control of MS patients compared to the standard program

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/10/2021, Research Ethics Committee from Wroclaw Medical University (1 Pasteur Street, 50-367, Wroclaw, Poland; +48 (0)717841014; bioetyka@umed.wroc.pl), ref: KB-807/2021

Study design
Prospective randomized clinical study with follow-up analysis

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Multiple sclerosis

Interventions
After baseline assessments, the participants will be randomly assigned to:
1. Vojta therapy
2. Standard rehabilitation training

The individuals receiving the treatment will be blinded. A computer-generated list of random numbers will be used and concealed from the researchers enrolling and assessing the participants. The outcome assessors and data analysts will be kept blinded to the allocation

The treatment protocol in the first group will include NDT Vojta exercises (once a day, three days a week) within 3 weeks. Each session will consist of a 40-min Vojta therapy protocol based on three exercises: crawling reflex and 1st phase and 2nd phase rolling reflex. The three face to face sessions will be made by the principal investigator. The participants in the second group will receive the standard rehabilitation program (50 minutes, once a day, three days a week) within 3 weeks, including balance exercises targeting core stability, exercises of coordination and proprioceptive neuromuscular facilitation (PNF) as well as individual sessions using the Bobath concept.

Intervention Type
Behavioural

Primary outcome measure
Gait analysed using a medical treadmill at baseline, 4, 8 and 16 weeks

Secondary outcome measures
1. Pain assessed with the Visual Analogue Scale at baseline, 4, 8 and 16 weeks
2. Balance and postural control assessed with the Berg Balance Scale (BBS) and the Tinetti Test at baseline, 4, 8 and 16 weeks
3. Postural control measured using the Timed Walking Test and 12-item Multiple Sclerosis Walking Scale at baseline, 4, 8 and 16 weeks

Overall study start date
16/08/2021

Completion date
30/12/2023

Eligibility

Key inclusion criteria
1. Final diagnosis of MS (by McDonald's criteria)
2. Relapsing-remitting stage of MS
3. Walkability with or without assistance (4.0-6 in Expanded Disability Status Scale [EDSS])

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Younger than 18 years old
2. Progressive MS
3. Phase outbreak or outbreak in the 3 months before the study
4. Medication that prevents or limits the performance of the locomotion reflex
5. Non-treated arterial hypertension
6. Cardiopulmonary incompetence
7. Pregnancy
8. Cancer
9. Active infections
10. Hepatitis B and HIV infection
11. Severe articular degeneration, including patients eligible for orthopedic surgery
12. Advanced osteoporosis
13. A history of stroke and Parkinson disease

Date of first enrolment
07/03/2022

Date of final enrolment
28/07/2023

Locations

Countries of recruitment
Poland

Study participating centre
University of Opole
Institute of Health Sciences
68 Katowicka Street
Opole
Poland
45-065

Study participating centre
Małgorzata Fuchs Fizjoterapia
7 Grota Roweckiego
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Sponsor information

Organisation
Opole University

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Institute of Health Sciences
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Sponsor type
University/education

Website
https://wnoz.uni.opole.pl/

ROR
https://ror.org/04gbpnx96

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Nowoczesna Fizjoterapia Neurar

Results and Publications

Publication and dissemination plan
Publications in peer-reviewed journals

Intention to publish date
30/12/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request (j.taradaj@awf.katowice.pl)

IPD sharing plan summary
Available on request