ISRCTN11301892 https://doi.org/10.1186/ISRCTN11301892

Biological impact of an intensive 21-day spa recovery program on quality of life and cell health in Parkinson's disease

Submission date
11/05/2026

Recruitment status
No longer recruiting

Registration date
12/05/2026

Overall study status
Completed

Last Edited
12/05/2026

Condition category
Nervous System Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator

Contact name
Prof Martin Kolisek

Contact details
BioMed Martin, JLF UK, Comenius University in Bratislava
Mala Hora 4D
Martin
Slovakia
03601
+421 (0)950577501
martin.kolisek@uniba.sk

Type(s)
Scientific

Contact name
Dr Alena Korencikova

Contact details
SLKP Piešťany
Kúpeľný ostrov 29
Piešťany

Slovakia
92129
+421 (0)337757733
akorencikova@ensanahotels.com

Type(s)
Public

Contact name
Mrs Lucia Rahelova

Contact details
BioMed JLF UK
Mala Hora 4D
Martin
Slovakia
03601
+421 (0)43 9279698
lucia.rahelova@uniba.sk

Additional identifiers

Study information

Scientific Title
Multimodal adjuvant therapy of Parkinson's disease and its impact on quality of life and the deep proteomic network

Study objectives
The objective of this study is to resolve the systemic molecular architecture of recovery following the 21-day Parkinson Spa Recovery (PSR) protocol, an intensive program integrating balneotherapy, neurophysiotherapy, and targeted nutrition.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/10/2023, Ethical Committee at Jessenius Faculty of Medicine in Martin, Comenius University in Bratislava (Mala Hora 4A, Martin, 03601, Slovakia; +421 (0)432633604; jana.mahutova@uniba.sk), ref: EK59/2023

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Prevention, Supportive care, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Parkinson's disease

Interventions
Participants completed a 21-day inpatient multimodal PSR rehabilitation programme at the Slovak Health Spa Piešťany. The regimen totalled 63 therapeutic interventions (three sessions daily) across three specialised modules:
1. Balneotherapy and physical rehabilitation: daily balneological treatments utilised natural medicinal mineral water or hydrogen-sulphide-rich peloid therapy. Bespoke physiotherapy sessions (2×/week) addressed individual musculoskeletal imbalances, focusing on gait dynamics and postural stability. Structured group exercises (3×/week) incorporated aquatic therapy, hydro-cycling, neuro-specific gym training, and Nordic walking. Adjunctive therapies, including hydromassage, parafango (paraffin-peloid), magnetotherapy, laser therapy, and phototherapy (biolamp), were administered according to individual clinical indications.
2. Sensory modulation: a multi-sensory stimulation protocol provided visual cues (high-contrast floor markers), auditory stimuli (rhythmic and meditative acoustics), and somatosensory inputs (aromatherapy) to facilitate motor planning and emotional regulation.
3. Nutraceutical intervention and hydropinic (mineral water) therapy: participants adhered to a controlled dietary regimen integrating principles of the Mediterranean-DASH Intervention for Neurodegenerative Delay (MIND) diet. The nutritional protocol was standardised to a mean daily energy intake of 2000 kcal, administered across three equal meals. The target macronutrient distribution was 20% protein (100 g), 60% carbohydrates (300 g), and 20% lipids (44.4 g), aligning with established Acceptable Macronutrient Distribution Ranges (AMDR, IOM 2002 /2005). This regimen emphasised neuroprotective food groups, including leafy greens, berries, and healthy fats, while restricting processed sugars and saturated lipids. Hydropinic therapy consisted of drinking 100 ml natural medicinal water 1-3 times daily (titrated to individual tolerance). To optimize mineral absorption and metabolic influence, servings were administered 30 minutes pre-prandially.

Intervention Type
Other

Primary outcome(s)
1. Patient-reported quality of life, objective motor performance, and functional autonomy in activities of daily living, measured using self-reported 39-item Parkinson's disease questionnaire (PDQ-39), 16-item, 3 -domain Modified Parkinson Activity Scale (mPAS), and 11-point Schwab and England Activities of Daily Living Scale (S&E ADL) at before treatment (T0), after treatment (21 days) (T1), and for PDQ-39 also 4 weeks post treatment (T2)

2. Basic clinical biochemical and hematological parameters measured using various clinically certified methods: Absolute Basophil Count (109/L), Absolute Eosinophil Count (109/L), Absolute Lymphocyte Count (109/L), Absolute Monocyte Count (109/L), Absolute Neutrophil Count (109/L), Atherogenic Index Basophils (%), C-Reactive Protein (mg/L), Eosinophils (%), Hematocrit Hemoglobin (g/L), Interleukin 1-alpha (pg/mL), Interleukin 1-beta (pg/mL), Interleukin 6 (pg/mL), Lymphocytes (%), Mean Corpuscular Hemoglobin (pg), Mean Corpuscular Hemoglobin Concentration (g/L), Mean, Corpuscular Volume (fL), Monocytes (%), Neutrophils (%), Platelet Distribution Width (fL), Platelets (109/L), Red Blood Cells (1012/L), S-Uric Acid (µmol /L), S-Alanine Aminotransferase (µkat/L), S-Aspartate Aminotransferase (µkat/L), S-Calcium (mmol/L), S-Creatine Kinase (µkat/L), S-Creatinine (µmol/L), S-Glucose (mmol/L), S-High-Density Lipoprotein (mmol/L), S-Cholesterol (mmol/L), S-Potassium (mmol/L), S-Low Density Lipoprotein Cholesterol (mmol/L), S-Magnesium (mmol/L), S-Sodium (mmol/L), S-non-High Density Lipoprotein Cholesterol (mmol/L), S-Phosphate (mmol/L), S-Triglycerides (mmol/L), S-Urea (mmol /L), White Blood Cells (109/L) at before treatment and 21 days after treatment (T1)

3. Qualitative and quantitative features of plasma proteome measured using deep aptamer proteomics profiling at before (T0) and 21 days after (T1)

Key secondary outcome(s)

Completion date
29/05/2025

Eligibility

Key inclusion criteria
Parkinson's disease patients with mild-to-moderate impairment, classified as Hoehn and Yahr stages 1-3

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
40 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
32

Key exclusion criteria
1. Infectious diseases: infectious diseases transmissible to humans and being a carrier of pathogens; all diseases in the acute stage

2. Cardiovascular conditions: clinical signs of circulatory failure, post-deep vein thrombosis conditions within 3 months of recovery, post-superficial thrombophlebitis conditions within six weeks of recovery, hypertension with diastolic pressure above 16 kPa (120 mm Hg)
3. Metabolic conditions: labile or decompensated diabetes mellitus, frequently recurring profuse bleeding of any kind, cachexia (wasting syndrome) of any kind, malignant tumors during and after treatment with clinically confirmed signs of disease progression
4. Neurological and psychiatric conditions: epilepsy (except for cases where no seizures have occurred in the last year),
active attacks or phases of psychosis and mental disorders with antisocial behavior or impaired communication, alcohol or drug dependency, dementia
5. General and physiological conditions: stage III urinary and fecal incontinence, enuresis nocturna (bedwetting), pregnancy, non-healing skin defects of any origin

Date of first enrolment
17/02/2024

Date of final enrolment
18/09/2024

Locations

Countries of recruitment
Slovakia

Sponsor information

Organisation
Slovak Research and Development Agency

ROR
https://ror.org/037nx0e70

Funder(s)

Funder type

Funder Name
Agentúra na Podporu Výskumu a Vývoja

Alternative Name(s)
Slovak Research and Development Agency, Agentúra na podporu výskumu a vývoja, Bratislava, Agentúra na podporu výskumu a vývoja, Slovak Research and Development Agency (SRDA), Slovak Research and Development Agency (Slovakia), APVV, SRDA

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
Slovakia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available