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The chronic effects of hydrogen-rich water on people with Parkinson's disease

Submission date
05/05/2023

Recruitment status
No longer recruiting

Registration date
10/05/2023

Overall study status
Completed

Last Edited
20/11/2023

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
Parkinson's disease is a condition in which parts of the brain become progressively damaged over many years. The 3 main symptoms of Parkinson's disease are involuntary shaking of particular parts of the body (tremor), slow movement, stiff and inflexible muscles.

If Parkinson’s disease (PD) were transmissible, it would be labelled a pandemic. PD is the second most common neurodegenerative disease in the world, there is no known cure or disease modifying drugs available for PD, and cases globally are expected to more than double in the next 20 years. It is important that therapeutic applications which aid in the reduction of symptoms of PD are explored, which would ultimately improve the quality of life for people with Parkinson’s (PwP).

The study would like to investigate if hydrogen rich water impacts motor and non-motor symptoms of PD, physical activity levels, and blood markers of inflammation/neuro-inflammation, and oxidative stress.

Who can participate?
1. All participants must have a diagnosis of PD by a Neurologist or Geriatrician.
2. All participants must be at stage 2 or stage 3 on the Hoehn and Yahr (H&Y) scale. Stage 1 is too mild and stages 4 and 5 could potentially be too severe for appropriate study participation.
3. Male or female.
4. Able to attend the School of Sport and Exercise Sciences facilities
5. Able to consume one litre of water per day
6. Participants' disease state must be stable over the past two months

What does the study involve?
Consuming HRW or PLA water (one litre per day) and wearing an activity tracker 24/7 for four weeks, followed by a one week washout period, then continuation of consumption of HRW or PLA water and wearing an activity tracker 24/7.

What are the possible benefits and risks of participating?
Benefits:

This will enable researchers to determine if HRW improves symptoms of Parkinson's disease
Risks:
Venous blood sampling
Venous blood will be taken in order to assess the participant for markers of inflammatory status and antioxidant capacity in the blood. It is possible the participant may suffer from bruising from the puncture site

Functional mobility and aerobic capacity and endurance testing (6 minute walk test and Timed Up and Go Test (TUG)
Participants will be required to walk back and forth between two points as far as they can within six minutes. The route will be free of potential trip hazards and chairs will be spaced in case a participant needs to rest.

Where is the study run from?
University of Kent, School of Sport and Exercise Sciences (UK)

When is the study starting and how long is it expected to run for?
November 2022 to March 2024

Who is funding the study?
Osmio Water Technology (UK)

Who is the main contact?
Kimberly Dargan, kvd4@kent.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Mrs Kimberly Dargan

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
UoK SSES REAG Ref No. 23_20_23

Study information

Scientific Title
The chronic effects of hydrogen-rich water on motor and non-motor functions and blood biomarkers in people with Parkinson's disease

Study objectives
1. Hydrogen rich water (HRW) lowers POMS Total Mood Disturbance score (indicative of a more stable mood profile) compared to placebo water (PLA)
2. HRW improves cognitive function compared to PLA
3. HRW improves dexterity compared to PLA
4. HRW reduces inflammation/neuro-inflammation compared to PLA
5. HRW reduces oxidative stress more than PLA
6. HRW reduces sedentary time more than PLA
7. HRW increase BDNF more than PLA

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/02/2023, University of Kent School of Sport and Exercise Sciences Research Ethics and Advisory Group (REAG) (SSES, University of Kent, Chipperfield Building, Kent, CT2 7PE, UK; ssesethics@kent.ac.uk), ref: 23_20_23

Study design
Single-centre randomized crossover single-blind study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
The trial is 9 weeks in total. For 4 weeks 1 l of HRW or PLA will be consumed daily (a total of 28 days). There is a 1-week wash-out period, followed by another 4 weeks of 1 l of HRW or PLA daily consumption (a total of 28 days.) The order of water consumption (HRW or PLA) will be randomised using computer randomisation software. The participant will be unaware of which water they are consuming until study completion. All participants will receive HRW or PLA. Mood state (measured by POMS), cognitive function (measured by a Flanker Compatibility Task), and dexterity (using a Purdue Pegboard Test) will be assessed and blood samples (to assess for

markers of inflammation/neuro-inflammation, oxidative stress and BDNF), functional mobility will be assessed using at timed up and go test, and aerobic capacity and endurance will be measured using a 6-min walk test will be taken at baseline, after 1 week, after 4 weeks. Then again at week 5 (baseline before other intervention), then at week 6 , and then at week 9. An activity tracker will be worn for the total of 8 weeks of water consumption.

Intervention Type
Supplement

Primary outcome(s)
Cognitive function and manual dexterity to be measured using a Purdue Pegboard Test (the three-trial administration test-retest will be used to increase reliability) at baseline, after 1 week, after 4 weeks of HRW and PLA consumption.

Key secondary outcome(s))
Measures 1-4 will be assessed at time points of: baseline, week 1, week 4, week 5, week 6, week 9:
1.Transient mood measured using a Profile of Mood States (POMS)– Short Form.
2. Visual attention measured using The Flanker Compatibility Task
3. The burden of non-motor symptoms, including non-motor fluctuations, using the Movement Disorder Society Non-Motor Rating Scale
4. Blood markers of oxidative stress, inflammation/neuro inflammation and BDNF will measured in serum or plasma derived from venous blood samples.
5. Physical activity levels will be measured using an activity tracker worn for a total of eight weeks.

Completion date
01/03/2024

Eligibility

Key inclusion criteria
1. All participants must have a diagnosis of PD by a Neurologist or Geriatrician
2. All participants must be at stage 2 or stage 3 on the Hoehn and Yahr (H&Y) scale. Stage 1 is too mild and stages 4 and 5 could potentially be too severe for appropriate study participation
3. Male or female
4. Able to consume 1 l of HRW or PLA per day
5. All participants' disease should be in a stable state for the past 2 months

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Participants whose Parkinson's is not controlled.
2. Participants who are at stage 1, stage 4 and stage 5 of the H&Y scale.
3. Participants who cannot consent for themselves.

Date of first enrolment
10/05/2023

Date of final enrolment
01/01/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Kent
School of Sport and Exercise Sciences
Chipperfield Building
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CT2 7PE

Sponsor information

Organisation
University of Kent

ROR
https://ror.org/00xkeyj56

Funder(s)

Funder type
Industry

Funder Name
Osmio Water Technology

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 Kimberly Dargan (kvd4@kent.ac.uk) after completion and publication of study results (de-identified participant data).

IPD sharing plan summary
Available on request