

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

Submission date 05/05/2023	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/05/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/11/2023	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

ORCID ID

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised cross over trial

Study setting(s)

Home, University/medical school/dental school

Study type(s)

Treatment

Participant information sheet

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

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 a 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 measure

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.

Secondary outcome measures

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 be 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.

Overall study start date

01/11/2022

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

Age group

Adult

Sex

Both

Target number of participants

20

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**

England

United Kingdom

Study participating centre**University of Kent**

School of Sport and Exercise Sciences

Chipperfield Building

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Sponsor information**Organisation**

University of Kent

Sponsor details

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Sponsor type

University/education

Website

<https://www.kent.ac.uk/research-innovation-services/contact-research-and-innovation-services>

ROR

<https://ror.org/00xkeyj56>

Funder(s)**Funder type**

Industry

Funder Name

Osmio Water Technology

Results and Publications**Publication and dissemination plan**

Planned publication in a peer-reviewed journal

Intention to publish date

01/06/2024

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