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Assessing the feasibility of a supervised exercise rehabilitation intervention with behavioural and motivational support, for people with postural orthostatic tachycardia syndrome

Submission date 06/04/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/04/2020	**Overall study status** Completed	
Last Edited 24/06/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Current plain English summary:
Background and study aims
Postural Orthostatic Tachycardia Syndrome (POTS) can seriously affect well-being and quality of life, due to its many disabling symptoms. The condition mostly (but not only) affects women aged 13 to 50. People with POTS have an abnormal heart rate rise when they stand up, with symptoms including palpitations, dizziness, fainting, and long-lasting fatigue. Attending education, earning a living, and caring for dependents can be severely affected, and the impact on the healthcare system is significant. Medical treatment is not always effective for POTS, but lifestyle interventions like exercise may help some people. The aim of this study is to find out if people with POTS will enrol on, and complete, a remotely supervised exercise programme.

Who can participate?
Patients 18 to 60 years of age with a confirmed diagnosis of Postural Orthostatic Tachycardia Syndrome (POTS), and able to attend a PULSE centre 3 times over 7 months for outcomes assessments.

What does the study involve?
Participants will be invited to a research assessment, lasting up to two hours, with an exercise specialist at their local cardiac rehabilitation centre. This will be repeated 4 and 7 months later. At all three assessments, participants will be asked to complete the following:
1. An exercise bike assessment: 6 to 10 minutes (or as long as they can manage) pedalling on a recumbent (like sitting in an armchair) exercise bike.
2. 10-minute stand test (optional): participants will probably have done this test before when they found out they had POTS. They will be asked to stand for up to 10 minutes (or for as long as they can manage) while the researchers monitor their pulse.
3. Questionnaires: the researchers will ask participants to fill in four different questionnaires to

find out about their quality of life, tiredness, how they feel about themselves, dizziness and other POTS symptoms.
After the first research assessment, participants will be assigned by chance (randomised) to one of two groups for 12 weeks: the PULSE programme, or the usual care group (also known as the 'control group'), who will have an advice session with an exercise specialist. Participants or the research team will not be able to choose which group they are in. This is decided by a computer programme at random so that the results of the study are not influenced by peoples' preference. The researchers will compare how the two groups get on. They will test whether people want to be involved, can tolerate the exercise, and if symptoms and quality of life improve over time. The study will help them to understand if the NHS should provide supervised physical activity programmes for people with POTS.

What are the possible benefits and risks of participating?
This study may not offer participants any direct benefit but the results will help people with POTS in the future. If any of the assessments find anything unusual with a participant's health, they will receive prompt and appropriate medical care and attention. Physical activity carries a very small risk of complications for patients with POTS. If participants were likely to be at high risk, their medical team would not have asked them to take part. Participants will be supervised by specialist staff and their programme will be designed to meet their specific needs. Physical activity is likely to cause some tiredness, breathlessness and sore muscles but this should get a bit easier each time they come. POTS symptoms may become worse for 4 to 6 weeks before they start to improve. The researchers do not anticipate any major risks to participants.

Where is the study run from?
1. University Hospitals Coventry & Warwickshire NHS Trust (UK)
2. Coventry University (UK)
3. Imperial College Healthcare NHS Trust (UK)

When is the study starting and how long is it expected to run for?
September 2019 to April 2023

Who is funding the study?
British Heart Foundation (UK)

Who is the main contact?
Dr Gordon McGregor
gordon.mcgregor@uhcw.nhs.uk

Previous plain English summary:
Background and study aims
Postural Orthostatic Tachycardia Syndrome (POTS) can seriously affect well-being and quality of life, due to its many disabling symptoms. The condition mostly (but not only) affects women aged 13 to 50. People with POTS have an abnormal heart rate rise when they stand up, with symptoms including palpitations, dizziness, fainting, and long-lasting fatigue. Attending education, earning a living, and caring for dependents can be severely affected, and the impact on the healthcare system is significant. Medical treatment is not always effective for POTS, but lifestyle interventions like exercise may help some people. The aim of this study is to find out if people with POTS will enrol on, and complete, a supervised exercise programme.

Who can participate?
Patients 18 to 40 years of age with a confirmed diagnosis of Postural Orthostatic Tachycardia Syndrome (POTS), and able to attend a PULSE centre 1-2 times/week for 8-12 weeks for exercise training

What does the study involve?
Participants will be invited to a research assessment, lasting up to two hours, with an exercise specialist at their local cardiac rehabilitation centre. This will be repeated 4 and 7 months later. At all three assessments, participants will be asked to complete the following:
1. An exercise bike assessment: 6 to 10 minutes (or as long as they can manage) pedalling on a recumbent (like sitting in an arm-chair) exercise bike.
2. 10-minute stand test (optional): participants will probably have done this test before when they found out they had POTS. They will be asked to stand for up to 10 minutes (or for as long as they can manage) while the researchers monitor their pulse.
3. Questionnaires: the researchers will ask participants to fill in four different questionnaires to find out about their quality of life, tiredness, how they feel about themselves, dizziness and other POTS symptoms.
After the first research assessment, participants will be assigned by chance (randomised) to one of two groups for 12 weeks: the PULSE programme, or the usual care group (also known as the 'control group'), who will have an advice session with an exercise specialist. Participants or the research team will not be able to choose which group they are in. This is decided by a computer programme at random so that the results of the study are not influenced by peoples' preference. The researchers will compare how the two groups get on. They will test whether people want to be involved, can tolerate the exercise, and if symptoms and quality of life improve over time. The study will help them to understand if the NHS should provide supervised physical activity programmes for people with POTS.

What are the possible benefits and risks of participating?
This study may not offer participants any direct benefit but the results will help people with POTS in the future. If any of the assessments find anything unusual with a participant's health, they will receive prompt and appropriate medical care and attention. Physical activity carries a very small risk of complications for patients with POTS. If participants were likely to be at high risk, their medical team would not have asked them to take part. Participants will be supervised by specialist staff and their programme will be designed to meet their specific needs. Physical activity is likely to cause some tiredness, breathlessness and sore muscles but this should get a bit easier each time they come. POTS symptoms may become worse for 4 to 6 weeks before they start to improve. The researchers do not anticipate any major risks to participants.

Where is the study run from?
1. University Hospitals Coventry & Warwickshire NHS Trust (UK)
2. Coventry University (UK)
3. Imperial College Healthcare NHS Trust (UK)

When is the study starting and how long is it expected to run for?
September 2019 to October 2021

Who is funding the study?
British Heart Foundation (UK)

Who is the main contact?
Dr Gordon McGregor
gordon.mcgregor@uhcw.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Gordon McGregor

ORCID ID
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
266145

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 43595, IRAS 266145

Study information

Scientific Title
PostUraL tachycardia Syndrome Exercise (PULSE): a randomised feasibility study

Acronym
PULSE

Study objectives
Current study hypothesis as of 11/06/2021:
1. Remotely supervised exercise rehabilitation with behavioural and motivational support is feasible and acceptable for people with POTS.
2. Assessment of physiological, clinical and health-related outcomes before and after an exercise rehabilitation programme is feasible and acceptable for people with POTS.

Previous study hypothesis:
1. Supervised exercise rehabilitation with behavioural and motivational support is feasible and acceptable for people with POTS.
2. Assessment of physiological, clinical and health-related outcomes before and after an exercise rehabilitation programme is feasible and acceptable for people with POTS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/03/2020, East Midlands - Nottingham 2 Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8035, +44 (0)207 104 8103; nottingham2.rec@hra.nhs.uk), REC ref: 20/EM/0077

Study design
Randomised; Both; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Rehabilitation, Cohort study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Postural orthostatic tachycardia syndrome

Interventions
Current interventions as of 25/10/2021:
Setting: Existing, fully equipped NHS Trust community cardiac rehabilitation centres with access to emergency equipment, and qualified/experienced staff and at the participants' homes for the remotely delivered intervention. Local transport will be provided for those who require assistance to attend outcomes assessments.

PULSE intervention arm: 12-week programme of 1-2 times weekly remotely supervised exercise rehabilitation with behavioural and motivational support. There are no accepted guidelines for exercise training in POTS; our intervention is based on existing evidence, our PPI and co-production sessions, and our centres' expertise in the provision of exercise for clinical populations, including some pilot work in POTS.

Individual assessment: Participants will attend a one hour, online one-to-one appointment, with a PULSE practitioner, to assess medical history, medication, and discussion of participant goals, expectations, fears and concerns.

Remotely supervised exercise programmes: Exercise training will be facilitated by a trained PULSE practitioner using:
1. Participant manual with details of the exercise programme, instruction on safe and effective exercise, and a logbook to record completed exercise. These materials will be provided to participants at the start of the intervention, along with any other equipment needed to carry out the exercises e.g. Therabands, Balls.
2. Live exercise sessions led by a PULSE practitioner to allow participants to exercise with other

participants and receive real time instruction and feedback.
3. Loan of a home exercise bike for the duration of the intervention, with an instructional video for participants to follow.

Participants will be invited to join an online platform through which the group will be able to access the exercise sessions. The same group will meet for weekly live online exercise sessions each lasting approximately 40-60 minutes.

In addition, on-demand videos will be uploaded to the platform which participants can watch and undertake in their own time. Number of video views and duration of each viewing will be used to assess adherence to the 12 week exercise rehabilitation programme.

Where possible participants will be requested to wear a heart rate monitoring device each time they carry out exercises as part of the programme.

Should a participant feel unwell during the live sessions, another trained practitioner ('co-pilot') will be available to take the participant out of a session and assess them individually. Any further steps required to ensure the participant's safety and wellbeing will be actioned by the 'co-pilot'.

'Functional fitness training' will aim to improve orthostatic tolerance and general musculoskeletal deconditioning. This type of training is targeted specifically at the components of physical fitness required for activities of daily living, making use of multi-plane motion, to improve agility, coordination, proprioception, balance and functional strength.

Prescribed exercise: Exercise will be versatile and individualised, incorporating cardiovascular and functional resistance training components. Interval or continuous cardiovascular exercise will be performed at a tolerable intensity (regulated with rating of perceived exertion [RPE] and symptoms) for a manageable time, focusing initially on exercises in the recumbent or semi-recumbent position to minimise orthostatic tachycardia. Gentle warm-up and cool down will be performed in the manner best suited to individual symptoms. Exercise intensity and time will be gradually increased, and upright exercise introduced as tolerated.

Lifestyle physical activity: During the 12-week programme participants will be encouraged to undertake self-directed, lifestyle physical activity in addition to the online sessions. This will help ensure that exercise is performed every other day. Activities such as swimming, walking and cycling will be encouraged for those in whom it is appropriate. It was important to our PPI groups, that exercise be sustainable and ultimately manageable within daily routines.

Behavioural and motivational support: The behavioural and motivational sessions will be delivered live online by a PULSE practitioner, with the aim of improving short and long-term adherence to exercise.

PULSE will draw on social cognitive approaches to behaviour change, including scrutiny of multiple interactions between environment, personal factors and behaviours. Based on the COM-B ('capability', 'opportunity', 'motivation' and 'behaviour') framework the researchers will address three basic aspects of peoples' lives: capability (increasing confidence through supervised practice), opportunity (identifying internal and external opportunities), and motivation (education, self-reflection, goal setting). They will focus on increasing participants' awareness of their priorities, through an investigation of the pros and cons of changing a specific behaviour (self-management e.g. exploring fear avoidance of exercise and strategies to break the fear-avoidance cycle), and assisting them to develop a specific plan (action planning, goal setting).

The PULSE practitioners will be trained to use open questions and motivational interviewing to assess patients' current beliefs and encourage behaviour change. In accordance with existing literature, it will be important to manage expectations. Previous work in POTS has indicated that symptoms may worsen for 4-6 weeks before lasting benefit is gained.

Previous interventions from 11/06/2021 to 25/10/2021:
Setting: Existing, fully equipped NHS Trust community cardiac rehabilitation centres with access to emergency equipment, and qualified/experienced staff and at the participants' homes for the remotely delivered intervention. Local transport will be provided for those who require assistance to attend outcomes assessments.

PULSE intervention arm: 12-week programme of 1-2 times weekly remotely supervised exercise rehabilitation with behavioural and motivational support. There are no accepted guidelines for exercise training in POTS; our intervention is based on existing evidence, our PPI and co-production sessions, and our centres' expertise in the provision of exercise for clinical populations, including some pilot work in POTS.

Individual assessment: Participants will attend a one hour, online one-to-one appointment, with a PULSE practitioner, to assess medical history, medication, and discussion of participant goals, expectations, fears and concerns.

Remotely supervised exercise programmes: Exercise training will be facilitated by a trained PULSE practitioner using:
1. Participant manual with details of the exercise programme, instruction on safe and effective exercise, and a logbook to record completed exercise. These materials will be provided to participants at the start of the intervention.
2. Live exercise sessions led by a PULSE practitioner to allow participants to exercise with other participants and receive real time instruction and feedback.
3. Loan of a home exercise bike for the duration of the intervention, with an instructional video for participants to follow.

Participants will be invited to join an online platform through which the group will be able to access the exercise sessions. The same group will meet for weekly live online exercise sessions each lasting approximately 40-60 minutes.

In addition, on-demand videos will be uploaded to the platform which participants can watch and undertake in their own time. Number of video views and duration of each viewing will be used to assess adherence to the 12 week exercise rehabilitation programme.

Where possible participants will be requested to wear a heart rate monitoring device each time they carry out exercises as part of the programme. Heart rate data will be recorded in real time and stored on the device. The data collected will be assessed and summarised when the device is returned at the end of the 12 week programme.

Should a participant feel unwell during the live sessions, another trained practitioner ('co-pilot') will be available to take the participant out of a session and assess them individually. Any further steps required to ensure the participant's safety and wellbeing will be actioned by the 'co-pilot'.

‘Functional fitness training’ will aim to improve orthostatic tolerance and general musculoskeletal deconditioning. This type of training is targeted specifically at the components of physical fitness required for activities of daily living, making use of multi-plane motion, to improve agility, coordination, proprioception, balance and functional strength.

Prescribed exercise: Exercise will be versatile and individualised, incorporating cardiovascular and functional resistance training components. Interval or continuous cardiovascular exercise will be performed at a tolerable intensity (regulated with rating of perceived exertion [RPE] and symptoms) for a manageable time, focusing initially on exercises in the recumbent or semi-recumbent position to minimise orthostatic tachycardia. Gentle warm-up and cool down will be performed in the manner best suited to individual symptoms. Exercise intensity and time will be gradually increased, and upright exercise introduced as tolerated.

Lifestyle physical activity: During the 12-week programme participants will be encouraged to undertake self-directed, lifestyle physical activity in addition to the online sessions. This will help ensure that exercise is performed every other day. Activities such as swimming, walking and cycling will be encouraged for those in whom it is appropriate. It was important to our PPI groups, that exercise be sustainable and ultimately manageable within daily routines.

Behavioural and motivational support: The behavioural and motivational sessions will be delivered live online by a PULSE practitioner, with the aim of improving short and long-term adherence to exercise.

PULSE will draw on social cognitive approaches to behaviour change, including scrutiny of multiple interactions between environment, personal factors and behaviours. Based on the COM-B (‘capability’, ‘opportunity’, ‘motivation’ and ‘behaviour’) framework the researchers will address three basic aspects of peoples’ lives: capability (increasing confidence through supervised practice), opportunity (identifying internal and external opportunities), and motivation (education, self-reflection, goal setting). They will focus on increasing participants’ awareness of their priorities, through an investigation of the pros and cons of changing a specific behaviour (self-management e.g. exploring fear avoidance of exercise and strategies to break the fear-avoidance cycle), and assisting them to develop a specific plan (action planning, goal setting).

The PULSE practitioners will be trained to use open questions and motivational interviewing to assess patients’ current beliefs and encourage behaviour change. In accordance with existing literature, it will be important to manage expectations. Previous work in POTS has indicated that symptoms may worsen for 4-6 weeks before lasting benefit is gained.

Original interventions:
Setting: Existing, fully equipped NHS Trust community cardiac rehabilitation centres with access to emergency equipment, and qualified/experienced staff. Safety will be ensured by condition-specific monitoring of exercise responses. Local transport will be provided for those who require assistance to attend outcomes assessments and intervention sessions.

PULSE intervention arm: 12-week supported programme of 1-2 times weekly supervised exercise rehabilitation with behavioural and motivational support. To ensure generalisability for future trials, provision will be based on current delivery models of exercise rehabilitation in cardiovascular disease. There are no accepted guidelines for exercise training in POTS; our intervention is based on existing evidence, our PPI and co-production sessions, and our centres’ expertise in the provision of exercise for clinical populations, including some pilot work in POTS.

Individual assessment: Participants will attend a one hour, one-to-one appointment, with a PULSE practitioner, to assess medical history, medication, physical activity history, and discussion of participant goals, expectations, fears and concerns.

Centre-based gym programme: For the first six weeks, exercise will be undertaken solely in a controlled environment with carefully staged progression in response to participant tolerance and symptoms. For those that are able, moderate-intensity dynamic cardiovascular exercise will be performed, aimed at chronically increasing blood volume and left ventricular stroke volume, and facilitating training-induced bradycardia. In addition, 'functional fitness training' will aim to improve orthostatic tolerance and general musculoskeletal deconditioning. This type of training is targeted specifically at the components of physical fitness required for activities of daily living, making use of multi-plane motion, to improve agility, coordination, proprioception, balance and functional strength.

Prescribed exercise: exercise will be versatile and individualised, incorporating cardiovascular and functional resistance training components. Interval or continuous cardiovascular exercise will be performed at a tolerable intensity (regulated with rating of perceived exertion [RPE] and symptoms) for a manageable time, focusing initially on exercises in the recumbent or semi-recumbent position (e.g. rowing machine, recumbent cycle ergometer) to avoid orthostatic tachycardia. Gentle warm-up and cool down will be performed in the manner best suited to individual symptoms. Exercise intensity and time will be gradually increased, and upright exercise introduced as tolerated. Lifestyle physical activity: After six weeks of centre-based exercise has been safely completed, and/or individual exercise tolerance has been evaluated, participants will be encouraged to undertake self-directed, lifestyle physical activity in addition to the supervised sessions. This will help ensure that exercise is performed every other day. Activities such as swimming, walking and cycling will be encouraged for those in whom it is appropriate. It was important to our PPI groups, that exercise be sustainable and ultimately manageable within daily routines.

Behavioural and motivational support: the researchers recognise the importance of psychological support in POTS and will, therefore, incorporate comprehensive behavioural change and motivational strategies to improve adherence and compliance to exercise. POTS can be associated with significant psychological and social consequences which may amplify the condition. This was a very prominent theme from our PPI work. Every second week, before or after exercise, participants will receive a one-to-one, 30-minute behavioural and motivational session delivered by a PULSE practitioner, with the aim of improving short and long-term adherence to exercise.

PULSE will draw on social cognitive approaches to behaviour change, including scrutiny of multiple interactions between environment, personal factors and behaviours. Based on the COM-B ('capability', 'opportunity', 'motivation' and 'behaviour') framework the researchers will address three basic aspects of peoples' lives: capability (increasing confidence through supervised practice), opportunity (identifying internal and external opportunities), and motivation (education, self-reflection, goal setting). They will focus on increasing participants' awareness of their priorities, through an investigation of the pros and cons of changing a specific behaviour (self-management e.g. exploring fear avoidance of exercise and strategies to break the fear-avoidance cycle), and assisting them to develop a specific plan (action planning, goal setting).

The PULSE practitioners will be trained to use open questions and motivational interviewing to assess patients' current beliefs and encourage behaviour change. In accordance with existing literature, it will be important to manage expectations. Previous work in POTS has indicated that symptoms may worsen for 4-6 weeks before lasting benefit is gained.

Intervention Type
Other

Primary outcome(s)
Current primary outcome measure as of 11/06/2021:
Feasibility and process-related outcomes:
1. Number of patients screened, eligible, recruited, randomised, withdrawn, and retained until the end of follow up at 7 months
2. Method of recruitment with which patients enter the trial
3. Adherence to exercise rehabilitation programme
4. Length of time to complete specific supervised and unsupervised outcome assessments
5. Physiological, clinical, patient-reported outcomes to identify a primary outcome for a definitive trial until the end of follow up at 7 months
6. Acceptability of the interventions and the trial assessed during qualitative interviews before and after the 12-week intervention period

Previous primary outcome measure:
Feasibility and process-related outcomes:
1. Number of patients screened, eligible, recruited, randomised, withdrawn and retained until the end of follow up at 7 months
2. Adherence to exercise rehabilitation programme after 12 weeks
3. Length of time to complete each outcome assessment and the whole outcome assessment appointments at 4 and 7 month follow-ups
4. Willingness of participants to join non-POTS specific exercise rehabilitation programmes during 12 months of recruitment
5. Physiological, clinical, patient-reported outcomes to identify a primary outcome for a definitive trial until the end of follow up at 7 months
6. Acceptability of the interventions and the trial assessed during qualitative interviews before and after the 12-week intervention period

Key secondary outcome(s))
Physiological, clinical and patient-reported outcomes:
1. Graded recumbent cycle ergometer test at baseline, 4 and 7 month follow-ups
2. Increase in heart rate from supine to 10-minute stand at baseline, 4 and 7 month follow-ups
3. Symptoms measured using COMPASS 31 dysautonomia scale at baseline, 4 and 7 month follow-ups
4. Quality of life measured using EQ5D-5L at baseline, 4 and 7 month follow-ups
5. Fatigue measured using Fatigue Severity Scale at baseline, 4 and 7 month follow-ups
6. Self-efficacy measured using General self-efficacy scale at baseline, 4 and 7 month follow-ups
7. Heart rate response to exercise measured by continuous heart rate monitoring during the 12-week exercise intervention
8. Symptoms experienced during the 12-week exercise intervention
9. Adverse events in accordance with GCP until the end of follow up at 7 months

Completion date

30/04/2023

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 02/03/2022:
1. Aged 18 to 60 years
2. Confirmed diagnosis of POTS, and currently attending syncope out-patient clinics
3. Able to attend a PULSE centre 3 times over 7 months for outcomes assessments
4. Access to appropriate IT infrastructure at home – internet and internet-enabled device (device can be provided on loan if required)
5. Able to provide informed consent

Previous participant inclusion criteria from 11/06/2021 to 02/03/2022:
1. Aged 18 to 40 years
2. Confirmed diagnosis of POTS, and currently attending syncope out-patient clinics
3. Able to attend a PULSE centre 3 times over 7 months for outcomes assessments
4. Access to appropriate IT infrastructure at home – internet and internet-enabled device (device can be provided on loan if required)
5. Able to provide informed consent

Original participant inclusion criteria:
1. Adults 18 to 40 years of age
2. Confirmed diagnosis of POTS, and currently attending syncope out-patient clinics
3. Able to attend a PULSE centre 1-2 times/week for 8-12 weeks for exercise training
4. Able to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
44

Key exclusion criteria
Current participant exclusion criteria as of 25/10/2021:
1. Absolute contraindications to exercise as per international clinical guidelines
2. Any serious mental health/cognitive issue that will prevent engagement with study procedures or increase the risk of exercise complications

3. Unable to make suitable travel arrangements to outcomes assessments (taxis can be organised if required)
4. Currently undertaking structured exercise/physical activity equivalent to meeting current Chief Medical Officer guidelines (150 minutes moderate exercise per week or 75 minutes vigorous per week)
5. Previous randomisation in the present trial
6. Pregnancy*
7. Taken part in the co-creation workshops to design the PULSE intervention

*If a patient becomes pregnant during the study, they will be withdrawn from all the physical aspects (e.g. intervention, usual care, outcome measures) of the study. However, they can continue with the non-physical outcome measures if they wish.

The researchers will not exclude people with:
1. Hypermobility spectrum disorders/Ehlers Danlos Syndrome (Classical or Hypermobile)
2. Chronic fatigue syndrome
3. Anxiety or depression

Previous participant exclusion criteria from 11/06/2021 to 25/10/2021:
1. Absolute contraindications to exercise as per international clinical guidelines
2. Any serious mental health/cognitive issue that will prevent engagement with study procedures or increase the risk of exercise complications
3. Unable to make suitable travel arrangements to outcomes assessments (taxis can be organised if required)
4. Currently undertaking structured exercise/physical activity equivalent to meeting current Chief Medical Officer guidelines (150 minutes moderate exercise per week or 60 minutes vigorous per week)
5. Previous randomisation in the present trial
6. Pregnancy*
7. Taken part in the co-creation workshops to design the PULSE intervention

*If a patient becomes pregnant during the study, they will be withdrawn from all the physical aspects (e.g. intervention, usual care, outcome measures) of the study. However, they can continue with the non-physical outcome measures if they wish.

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2. Any serious mental health/cognitive issue that will prevent engagement with study procedures or increase the risk of exercise complications
3. Unable to make suitable travel arrangements
4. Currently undertaking structured exercise/physical activity equivalent to meeting current Chief Medical Officer guidelines (150 minutes moderate exercise per week or 60 minutes vigorous per week)
5. Previous randomisation in the present trial
6. Pregnancy*
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2. Chronic fatigue syndrome
3. Anxiety or depression

Date of first enrolment
04/05/2021

Date of final enrolment
30/12/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals Coventry & Warwickshire NHS Trust
Walsgrave General Hospital
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
Imperial College Healthcare NHS Trust
St Marys Hospital
Praed Street
London
United Kingdom
W2 1NY

Sponsor information

Organisation
University Hospitals Coventry and Warwickshire NHS Trust

ROR

https://ror.org/025n38288

Organisation
Coventry University

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation; Grant Codes: PG/19/22/34203

Alternative Name(s)
The British Heart Foundation, the_bhf, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Anonymised raw data will be available from the CI Dr Gordon McGregor (gordon.mcgregor@uhcw.nhs.uk) on reasonable request after publication of the final trial manuscript.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		22/02/2025	24/06/2025	Yes	No
Protocol article		19/10/2020	23/10/2020	Yes	No
Protocol article	Protocol update	07/05/2022	09/05/2022	Yes	No

Protocol article	Protocol for the intervention designed in the first stage of the study	15/08/2023	16/08/2023	Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes