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Time is of the essence: how starting upper-body aerobic exercise early after a spinal cord injury can affect heart health

Submission date
05/05/2023

Recruitment status
No longer recruiting

Registration date
02/06/2023

Overall study status
Completed

Last Edited
11/05/2026

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
This study is investigating the effects of spinal cord injury (SCI) on cardiovascular health and the impact of early initiated (i.e., 6 to 8 weeks after injury) upper-body exercise. Following SCI, the primary cause of illness and death is cardiovascular disease. This may be due to: 1. disruption to the autonomic nervous system, which is responsible for the involuntary control of your heart and blood vessels, or 2. lifestyle changes such as a reduced level of physical activity. Preventative measures against cardiovascular disease focus around increasing physical activity and promoting healthy long-term lifestyle changes. However, early rehabilitation for the maintenance of cardiovascular health is not currently part of the standard of care due to the lack of evidence to support this during the rehabilitation period. This period may represent an opportunity to maximize rehabilitation and improve cardiovascular health over the long-term. The primary goal of this study is to determine if 10 weeks of arm-crank exercise training, started early in the inpatient rehabilitation care pathway will improve cardiovascular disease risk factors, fitness, and quality of life after injury.

Who can participate?
Patients who after immediate care in local trauma centres are admitted to the Midlands Centre for Spinal Injuries (MCSI) for inpatient rehabilitation after sustaining a spinal cord injury.

What does the study involve?
This is a longitudinal study, where assessments will be performed across four timepoints. The first three assessment visits (A1-A3) will last approximately 4 hours. The A4 assessment will be no longer than 45 minutes. The A4 assessment will be no longer than 45 minutes. We plan to assess changes in health outcomes following injury, with measurements taken as soon as possible after arrival at the Midlands Centre for Spinal Injuries at the Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust. The second assessment will be performed prior to starting the exercise intervention or standard of care rehabilitation. Following this, participants will be randomly assigned to receive standard of care or standard of care plus a

personalised moderate-intensity upper-body exercise intervention for 10 weeks. There will be a follow up assessment 6 months after discharge from in-patient rehabilitation for Health Related Quality of Life only.

What are the potential benefits and risks of participating?
The costs of all tests, examinations and interventions as part of this study will be provided at no cost to participants. Participants will have the opportunity to take part in a study that uses world class equipment and facilities whilst improving our knowledge of the impact of spinal cord injury on cardiovascular health and how early initiated exercise might influence this. It is currently unknown whether being randomly assigned to the exercise intervention will provide a personal therapeutic benefit for participants. However, others may benefit from the overall conclusions to be drawn from the results of this study. At the request of the participant, they will be able to obtain information on how their health has changed following injury and how their bodies have responded to exercise or standard of care rehabilitation.

All assessments will take place in a controlled clinical/research environment. Every effort will be made to ensure safety, privacy, and comfort. All procedures will be conducted by experienced and trained members of the research team. These procedures offer minimal risks, however, the following risks/discomforts that could be associated with these procedures are outlined below:
1. The adhesive electrodes (stickers) used for the activity monitor and ECG may cause mild discomfort when removed. We will take care to ensure your comfort with placement and removal of these. Experiencing any skin irritation will result in advice for alternate sites to place the stickers or provide participants with a fabric chest strap to attach the activity monitor to instead, given this is worn for a prolonged period of time.
2. The blood sample may cause a bruise and there is a potential risk of infection. These risks will be minimised by following good clinical practice. Participants may experience some light-headedness or headaches as a result of the overnight fast for the blood samples. This is equivalent to missing breakfast and is the minimal standardisation procedure for collecting fasting blood samples. Participants will be able to eat immediately once the blood sample procedure has been completed.
3. The ultrasound procedures are non-invasive and offer minimal risk. Participants may experience some discomfort due to the cold gel or because the assessments require you to lie on a procedure bed for an extended period of time. Participant positioning will be changed as necessary to ensure you are comfortable and maintain skin integrity. There is a very small risk that participants might fall out of bed (e.g., due to strong, involuntary spasms), though steps will be taken to ensure this does not occur (e.g., using guard rails where appropriate).
4. Participants may experience some discomfort with the cuff inflation around your upper-arm when measuring blood pressure. There are no known risks associated with this short-lived restriction of blood flow to the arm. It is possible participants may feel brief numbness and/or tingling in your hand, and a “pins and needles” sensation upon cuff deflation. These sensations should only last a few minutes.
5. Performing any form of vigorous-intensity exercise carries a minor risk. Risks include sensations of fatigue, physical exhaustion and fainting. The sensation of fatigue is short-lived and will subside in a few minutes upon stopping exercise. The risk of a cardiovascular event (such as a heart attack) is extremely low, approximately a 0.01% chance. You will warm up before each exercise bout and will be closely monitored throughout for known indications for stopping exercise [including sustained maximum heart rate, pain in the chest (angina), confusion etc.]. A first aid trained member of staff (including cardiopulmonary resuscitation training) will be present during the initial exercise sessions and all maximal exercise assessments. The MCSI and School of Sport, Exercise and Rehabilitation Sciences are both equipped with an automated defibrillator in close proximity to the space where testing will take place. There is a risk you may experience mild muscle soreness after the arm cycling exercise. You are free to stop and rest at

any point during the exercise sessions and are also free to stop the exercise intervention should you feel discomfort and wish to stop/withdraw from the study.
6. If participants have a higher-level spinal cord injury (above the sixth thoracic segment) then there is an increased risk of experiencing both high and low blood pressure. High-blood pressure is due to a condition called autonomic dysreflexia, which is triggered by a stimulus below the level of injury (e.g., full bladder). Participants will be asked to empty their bladder prior to any assessments. Participants may also feel faint or nauseous after exercise or upon moving from lying flat to a seated position. Blood pressure will be measured before and after exercise performed in clinic and the supervising member of staff will be trained to identify signs and symptoms of blood pressure instability, along with appropriate mitigation strategies if necessary.
7. Participants may experience some negative emotions when completing questionnaires that relate to your current mood or ability to perform activities of daily living. If participants are worried about any aspect of your physical or mental health then we advise you to discuss this with a member of the clinical care team or relevant healthcare practitioner. In addition, below is contact information for UK organisations that provide emotional support for people experiencing distress.

Where is the study run from?
The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust and the University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
November 2022 to June 2026

Who is funding the study?
Heart Research United Kingdom (HRUK)

Who is the main contact?
Dr Tom Nightingale (Assistant Professor), T.E.Nightingale@bham.ac.uk
Dr Shane Balthazaar (Postdoctoral Research Fellow), S.J.T.Balthazaar@bham.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
315098

Central Portfolio Management System (CPMS)
54496

Sponsor reference number
RG_22-091

Study information

Scientific Title
Time is of the essence: the impact of early initiated upper-body aerobic exercise on cardiovascular health following spinal cord injury

Study objectives
Patients with spinal cord injury (SCI) who perform 10 weeks of arm-crank exercise training (ACET) early in the inpatient rehabilitation care pathway (i.e., subacute, 6 to 8 weeks) will display improved cardiovascular (CV) health relative to usual standard of care. We also expect that the cardiohaemodynamic benefits of upper-body exercise will persist beyond patient discharge.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 09/11/2022, Wales Research Ethics Committee 2 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, CF11 9AB, UK; +44(0)292 2940930; Wales.REC2@Wales.nhs.uk), ref: 22/WA/0329

Primary study design
Interventional

Study design
Single-centre single-blind randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Sub-acute spinal cord injury

Interventions
Current interventions as of 10/06/2025:
This study will involve a total of four assessment visits (~4 hours each); with two taking place before (A1, A2) and one immediately after a 10-week exercise intervention (or standard of care control) (A3). Following another visit 36 weeks after discharge from the hospital (A4) will be for Health Related Quality of Life assessments only. These assessment visits can be split across two separate days if requested by the participant (either due to fatigue or perceived burden) or the clinical management team. During these visits, a trained phlebotomist will take a fasting (>10 hours) blood sample from a forearm vein. Central arterial stiffness (primary outcome measure) will be determined, along with ultrasound assessments performed by a trained sonographer to determine cardiac structure and function. Cerebrovascular outcomes will also be assessed (blood flow velocity and vessel diameter of extracranial arteries) as well as cognitive function, using a shortened neuropsychological test battery. Participants will be asked to complete three health-related quality of life questionnaires and wear devices to capture heart rhythm disturbances, heart rate variability and blood pressure instability over a 24-hour period. For A2-A3, participants will also be asked to wear a physical activity monitor for 5 days, perform a cardiopulmonary exercise test (CPET) to exhaustion on an arm-crank ergometer and undergo a motor function assessment to determine sitting balance. Participants will also be asked to complete a usability and satisfaction questionnaire at the end of the intervention period. Participants will be invited to participate in two, one-to-one, semi-structure interviews via Zoom at completion of the intervention and at follow-up to discuss their views on the intervention received and the impact of the intervention on their recovery and integration into the community. In person focus groups will also be performed with staff (clinicians, occupational therapists, and physical therapists) involved in clinical/care/rehabilitation of patients at the Midland Centre for Spinal Injuries (MCSI) upon study completion to ascertain the acceptability of the intervention, trial design and outcome measures, and the staff's experiences during the trial.

After A2, eligible consenting participants will be randomly allocated (1:1) to a moderate-intensity arm-crank exercise training (ACET) group or a standard of care only control group. Both groups will continue to participate in standard care throughout the duration of their inpatient rehabilitation stay, which will consist of muscle strengthening, balance training, and mobility training (e.g., transferring, performing activities of daily living) and will be supervised by a physiotherapist. Participants in the ACET group will initially perform 3 x 30 minutes per week of moderate-intensity arm-crank exercise, in keeping with SCI-specific exercise guidelines to improve cardiometabolic health. Participants will be allowed breaks in each exercise bout as

required. By the end of the first week, participants should be able to cycle continuously for 30 minutes. At 4 and 7 weeks, the opportunity to perform an additional exercise session will be given to the participant, so that during weeks 7 – 10 of the in intervention participants could be performing 5 x 30 minutes per week of moderate-intensity ACET. Exercise intensity will be prescribed as a power output that corresponds to ~55% and ~62% of each participants VO2peak for individuals with paraplegia and tetraplegia, respectively, determined from their baseline graded cardiopulmonary exercise test (CPET). These population specific values have been chosen as recent research suggests they more closely correspond to moderate-intensity exercise classifications than utilising non-disabled guidelines. Exercise intensity will be regulated during the ten-week intervention by capturing participants ratings of perceived exertion (RPE) at the end of each exercise session, with RPE's of 12-13 on a 6-20 Borg Scale corresponding to moderate-intensity exercise. The actual targets for duration, intensity and frequency may be adjusted by an exercise physiologist based on the participants tolerance to the training parameters. Consequently, the individualised nature of ACET prescription allows us to identify what exercise training load is broadly achievable for patients with sub-acute SCI (in keeping with the feasibility aim of this research trial). Blood pressure will be monitored before and after each exercise training bout in clinic, which will be supervised by a research nurse. If participants are discharged during the 10-week intervention period, participants will receive an arm-crank ergometer for continuing the intervention in their own homes. A member of the study team will visit the participants home to ensure proper set-up of the device and supervise the first home-based session to ensure the correct exercise intensity is adhered to. Participants will wear a chest-worn heart rate monitor and complete training logs for all arm-crank exercise sessions. Participants will receive a weekly phone call from a member of the study team to ensure compliance.

Previous interventions:
This study will involve a total of four assessment visits (~4 hours each); with two taking place before (A1, A2) and one immediately after a 10-week exercise intervention (or standard of care control) (A3), with another visit 36 weeks after discharge from the hospital (A4). These assessment visits can be split across two separate days if requested by the participant (either due to fatigue or perceived burden) or the clinical management team. During these visits, a trained phlebotomist will take a fasting (>10 hours) blood sample from a forearm vein. Central arterial stiffness (primary outcome measure) will be determined, along with ultrasound assessments performed by a trained sonographer to determine cardiac structure and function. Cerebrovascular outcomes will also be assessed (blood flow velocity and vessel diameter of extracranial arteries) as well as cognitive function, using a shortened neuropsychological test battery. Participants will be asked to complete three health-related quality of life questionnaires and wear devices to capture heart rhythm disturbances, heart rate variability and blood pressure instability over a 24-hour period. For A2-A4, participants will also be asked to wear a physical activity monitor for 5 days, perform a cardiopulmonary exercise test (CPET) to exhaustion on an arm-crank ergometer and undergo a motor function assessment to determine sitting balance. Participants will also be asked to complete a usability and satisfaction questionnaire at the end of the intervention period. Participants will be invited to participate in two, one-to-one, semi-structure interviews via Zoom at completion of the intervention and at follow-up to discuss their views on the intervention received and the impact of the intervention on their recovery and integration into the community. In person focus groups will also be performed with staff (clinicians, occupational therapists, and physical therapists) involved in clinical/care /rehabilitation of patients at the Midland Centre for Spinal Injuries (MCSI) upon study completion to ascertain the acceptability of the intervention, trial design and outcome measures, and the staff's experiences during the trial.

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Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 10/06/2025:
At three assessment visits (~4 hours each); with two taking place before (A1, A2) and one immediately after a 10-week exercise intervention (or standard of care control) (A3):
Arterial stiffness. Arterial pulse waveforms will be acquired at two locations (carotid and femoral arteries) simultaneously to determine pulse transit time and carotid-to-femoral pulse wave velocity (cfPWV) at A1-A3. The Vicorder (Smart Medical, UK) system will be used with standard vascular cuffs, which has been shown to be a quick and highly reproducible technique for assessing cfPWV that is operator independent.

Previous primary outcome measure:
At four assessment visits (~4 hours each); with two taking place before (A1, A2) and one immediately after a 10-week exercise intervention (or standard of care control) (A3), with another visit 36 weeks after discharge from the hospital (A4):

Arterial stiffness. Arterial pulse waveforms will be acquired at two locations (carotid and femoral arteries) simultaneously to determine pulse transit time and carotid-to-femoral pulse wave velocity (cfPWV) at A1-A4. The Vicorder (Smart Medical, UK) system will be used with standard vascular cuffs, which has been shown to be a quick and highly reproducible technique for assessing cfPWV that is operator independent.

Key secondary outcome(s)

Current secondary outcome measure as of 10/06/2025:
Three assessment visits (~4 hours each); with two taking place before (A1, A2) and one immediately after a 10-week exercise intervention (or standard of care control) (A3):
1. Cardiac structure and function. Transthoracic echocardiography (TTE) will be performed using a Vivid iq ultrasound system (General Electric Medical, Norway) in accordance with recommendations of the American Society for Echocardiography at A1-A4.
2. Extracranial vascular/Cerebrovascular measures. Blood velocity and vessel diameter of the left and right common carotid artery (CCA), internal carotid artery (ICA), external carotid artery (ECA), and vertebral artery (VA) will be measured via ultrasound at A1-A4.
3. Heart rhythm disturbances and BP instability over a 24-hour period. Continuous electrocardiogram (ECG) and periodic (day time: every 15 minutes; night-time: every hour) brachial BP measurements will be recorded using a Holter monitor and ambulatory BP monitor (Welch Allyn Mobil-O-Graph), respectively at A2-A4.
4. Heart rate variability (HRV). The non-stationary balance between sympathetic and parasympathetic branches of the cardiac autonomic nervous system will be assessed using ECG in accordance with best practice recommendations at A1-A4.
5. Cardiorespiratory fitness. VO2peak and peak power output will be determined using a graded CPET performed on an arm-crank ergometer until volitional exhaustion at A2-A4. Expired gases will be collected using a calibrated, portable metabolic cart (COSMED K5, Italy).
6. Cardiovascular disease risk blood biomarkers assessed at A1-A4. Biochemical outcomes include metabolic (i.e., triglycerides, total cholesterol, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, glucose, insulin) and inflammatory (i.e., leptin and adiponectin, interleukin-6, C-reactive protein) biomarkers.
7. Characterising weekly rehabilitation energy expenditure. Participants will wear an individually calibrated multisensor device for 5 days at A2-A4. The ActiheartTM, which incorporates tri-axial accelerometry and physiological signals, will be used to predict physical activity energy expenditure and minutes per week of activity within certain intensity thresholds (sedentary, light, moderate, and vigorous).
8. Motor function. Sitting balance will be determined via the Function in Sitting Test in SCI (FIST-SCI) at A2-A3.

Feasibility outcomes
All measured at the completion of the study:
1. Participant recruitment rate: the proportion of eligible patients who accept the invitation to participate in the research study.
2. Retention and adherence: the proportion of participants who complete the study and, for those in the intervention group, the proportion of intervention sessions completed.
3. The acceptability of the intervention, study design and outcome measures as well as participants' and clinicians' experiences with the intervention, assessed qualitatively using open-ended surveys and interview data for patient and staff groups analysed using thematic analysis.
4. Completion rates for each outcome measure evaluated to determine if an outcome measure should be removed.

Additionally, two assessments take place before (A1, A2) and one immediately after a 10-week exercise intervention (or standard of care control) (A3), with another visit 36 weeks after

discharge from the hospital (A4):
5. Health-related quality of life. Shoulder pain will be assessed weekly using the Wheelchair Users Shoulder Pain Index (WUSPI).
6. Bodily pain severity and interference will be assessed using the two-item SF-36 Pain subscale, capturing the past 4 weeks at A1-A4.
7. Subjective vitality (eudemonic well-being) and fatigue will be measured via the Subjective Vitality Scale and fatigue severity scale, respectively at A1-A4.
8. Cognitive function. A shortened neuropsychological test battery will be utilised that includes the Digit Span and Symbol Digit Modality Test (SDMT) to give a global indication of cognitive function at A1-A4.

Previous secondary outcome measure:
Four assessment visits (~4 hours each); with two taking place before (A1, A2) and one immediately after a 10-week exercise intervention (or standard of care control) (A3), with another visit 36 weeks after discharge from the hospital (A4)
1. Cardiac structure and function. Transthoracic echocardiography (TTE) will be performed using a Vivid iq ultrasound system (General Electric Medical, Norway) in accordance with recommendations of the American Society for Echocardiography at A1-A4.
2. Extracranial vascular/Cerebrovascular measures. Blood velocity and vessel diameter of the left and right common carotid artery (CCA), internal carotid artery (ICA), external carotid artery (ECA), and vertebral artery (VA) will be measured via ultrasound at A1-A4.
3. Heart rhythm disturbances and BP instability over a 24-hour period. Continuous electrocardiogram (ECG) and periodic (day time: every 15 minutes; night-time: every hour) brachial BP measurements will be recorded using a Holter monitor and ambulatory BP monitor (Welch Allyn Mobil-O-Graph), respectively at A2-A4.
4. Heart rate variability (HRV). The non-stationary balance between sympathetic and parasympathetic branches of the cardiac autonomic nervous system will be assessed using ECG in accordance with best practice recommendations at A1-A4.
5. Cardiorespiratory fitness. VO2peak and peak power output will be determined using a graded CPET performed on an arm-crank ergometer until volitional exhaustion at A2-A4. Expired gases will be collected using a calibrated, portable metabolic cart (COSMED K5, Italy).
6. Cardiovascular disease risk blood biomarkers assessed at A1-A4. Biochemical outcomes include metabolic (i.e., triglycerides, total cholesterol, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, glucose, insulin) and inflammatory (i.e., leptin and adiponectin, interleukin-6, C-reactive protein) biomarkers.
7. Characterising weekly rehabilitation energy expenditure. Participants will wear an individually calibrated multisensor device for 5 days at A2-A4. The ActiheartTM, which incorporates tri-axial accelerometry and physiological signals, will be used to predict physical activity energy expenditure and minutes per week of activity within certain intensity thresholds (sedentary, light, moderate, and vigorous).
8. Health-related quality of life. Shoulder pain will be assessed weekly using the Wheelchair Users Shoulder Pain Index (WUSPI). Bodily pain severity and interference will be assessed using the two-item SF-36 Pain subscale, capturing the past 4 weeks at A1-A4. Subjective vitality (eudemonic well-being) and fatigue will be measured via the Subjective Vitality Scale and fatigue severity scale, respectively at A1-A4.
9. Cognitive function. A shortened neuropsychological test battery will be utilised that includes the Digit Span and Symbol Digit Modality Test (SDMT) to give a global indication of cognitive function at A1-A4.
10. Motor function. Sitting balance will be determined via the Function in Sitting Test in SCI (FIST-SCI) at A2-A4.

Feasibility outcomes
All measured at the completion of the study:
1. Participant recruitment rate: the proportion of eligible patients who accept the invitation to participate in the research study.
2. Retention and adherence: the proportion of participants who complete the study and, for those in the intervention group, the proportion of intervention sessions completed.
3. The acceptability of the intervention, study design and outcome measures as well as participants' and clinicians' experiences with the intervention, assessed qualitatively using open-ended surveys and interview data for patient and staff groups analysed using thematic analysis.
4. Completion rates for each outcome measure evaluated to determine if an outcome measure should be removed.

Completion date
30/06/2026

Eligibility

Key inclusion criteria
For patients:
1. At least 18 years old
2. Males and females
3. Have had a motor-complete SCI (AIS A or B) at the cervical or thoracic level (between C5 - T12) within 3 months.
4. Are cleared by their medical team to begin standard of care rehabilitation
5. Can move their shoulders and arms voluntarily to operate the arm-crank ergometer
6. Compliance: understands and is willing, able and likely to comply with all study procedures and restrictions.
7. Consent: demonstrates an understanding of the study and willingness to participate, as evidenced by voluntary written informed consent

For staff:
1. Currently be a member of the medical team supporting sub-acute spinal cord injured patients at MCSI
2. Be at least 18 years old
3. Be involved in the clinical care/rehabilitation of patients (e.g., clinician, occupational therapist, or physical therapist)

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex

All

Total final enrolment
31

Key exclusion criteria
For patients:
1. Participants are pregnant (women who become pregnant will be advised to notify clinical staff, and upon notification, will be withdrawn from the trial)
2. Participants are under the age of 18 years
3. Participants have an SCI lower than the T12 neurological level
4. Participants have an SCI above the C5 neurological level, intubation, a trachea in situ or require mechanical ventilation
5. Have medical complications from the injury that in the opinion of the healthcare team would restrict or prevent the participation in exercise rehabilitation, pose an undue personal risk or introduce bias into the trial
6. Co-occurring traumatic brain injury or cognitive impairment that either impacts the ability to follow study instructions and/or provide informed consent
7. Unable to provide full informed consent

Date of first enrolment
01/06/2023

Date of final enrolment
06/06/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust
Gobowen
Oswestry
England
SY10 7AG

Study participating centre
University of Birmingham
School of Sport, Exercise and Rehabilitation Sciences (Building Y14),
College of Life and Environmental Sciences
Birmingham
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B15 2TT

Sponsor information

Organisation
University of Birmingham

Funder(s)

Funder type
Charity

Funder Name
Heart Research UK

Alternative Name(s)
HRUK

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

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		30/04/2025	01/05/2025	Yes	No
HRA research summary			28/06/2023	No	No