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Acute response to strength training in congenital heart disease

Submission date 09/02/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 10/02/2026	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 13/08/2026	**Condition category** Circulatory System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Congenital heart disease (ConHD) is common, and many young people are encouraged to be active, yet there is limited evidence on how their muscles and bodies respond during a single supervised strength-training session. This study aims to compare the immediate effects of one progressive strength-training workout on muscle strength and fatigue, as well as blood pressure, heart rate, oxygen levels and how the session feels, in young people with ConHD versus healthy peers.

Who can take part?

Young people aged 15–24 years with ConHD who are clinically assessed as New York Heart Association class I–II may take part. A comparison group of healthy young people matched by age, sex and training experience is also included. People are not eligible if, for example, they have significant ventricular dysfunction, severe aortic stenosis/outflow obstruction, documented life-threatening arrhythmias, cannot safely perform the required activity or CPET, or have non-cardiac conditions that impair mobility. Those aged 15–17 take part only with parent /guardian consent plus their own assent.

What does the study involve?

Each participant attends two visits at the University of Exeter, at least 96 hours apart (within 28 days). Visit 1 includes questionnaires, measurements (body composition, blood pressure, heart rate, oxygen saturation), muscle-strength tests and a cycling fitness test with a breathing mask (CPET) to set safe exercise limits. One-repetition maximum (1RM) is assessed to set training weights. Visit 2 is a single, supervised workout: 10-min warm-up, 10-min familiarisation, then about 30 minutes of progressive strength training (squats, standing calf raises, deadlifts, seated leg extensions) in three sets at 40% / 60% / 80% of 1RM (12/8/5 reps), followed by cooldown stretching. Blood pressure and short questionnaires on exertion/enjoyment are recorded around sets/exercises; heart rate and oxygen levels are monitored continuously. Simple muscle-soreness check-ins are collected on Days 1–3 after Visit 2. Participants are asked to avoid vigorous exercise for 48 hours before each visit.

What are the possible benefits and risks of taking part?

There is no guaranteed personal benefit, but findings may help design safer, more effective

strength-training guidance for young people with ConHD. Risks are expected to be low and similar to a supervised gym session, such as tiredness or temporary muscle soreness. Safety measures include CPET pre-screening, real-time monitoring, clear stop criteria (e.g., oxygen saturation below 90% or a 3–5% fall from baseline; heart rate above 85% of maximum; concerning symptoms/arrhythmia), and trained staff with first-aid and an AED on site. Participants may **withdraw at any time without giving a reason.

Where is the study carried out?
All study visits take place at the Children's Health and Exercise Research Centre (CHERC) laboratory and St Luke's Sports Centre, University of Exeter (St Luke's Campus, Exeter, UK).

When does the study start and how long will it run?
The planned study period is 01 September 2025 to 28 July 2026. For each participant, involvement covers two visits within 28 days plus three days of short follow-up messages after Visit 2.

Who is funding this study?
The study is funded by the University of Exeter and the China Scholarship Council; the University of Exeter is the study sponsor.

Who is the main contact?
Chief Investigator: Professor Craig Williams, c.a.williams@exeter.ac.uk
Study Coordinator: Mr Kunyu Hao, kh704@exeter.ac.uk

Contact information

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Integrated Research Application System (IRAS)
351713

Protocol serial number
242528

Study information

Scientific Title
Acute Response to Strength Training in Young People with Congenital Heart Disease

Acronym
ARSTConHD

Study objectives
The primary aim of this study is to compare difference in acute muscular responses (muscle strength and muscle fatigue) to a progressive strength training session in young people with congenital heart disease and healthy young people.

The secondary aim is to compare differences in acute physiological responses (blood pressure, blood oxygen saturation, and heart rate), perceived exertion, enjoyment responses, and delayed onset muscle soreness to different intensity strength training sessions in young people with congenital heart disease and healthy young people.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 19/08/2025, West Midlands – Coventry and Warwickshire REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048211; coventryandwarwick.rec@hra.nhs.uk), ref: 25/WM/0137

Primary study design
Interventional

Study design
This is a single-centre, quasi-experimental interventional study in which participants complete a single bout of progressive-intensity resistance training; allocation is non-random by disease status (young people with congenital heart disease vs matched healthy controls), with healthy

peers as the control; no allocation concealment or blinding is used (participants and exercise supervisors are unblinded); all assessments and training take place at the University of Exeter CHERC laboratory and St Luke's Sports Centre.

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
The acute response of strength training for young people with congenital heart disease

Interventions
Current interventions as of 13/08/2026:

This single-centre, quasi-experimental interventional study compares adolescents and young adults with congenital heart disease (ConHD) with matched healthy controls during a single supervised progressive-intensity resistance-training session: after Visit-1 screening and baseline tests (incl. CPET ramp protocol to determine HRmax, isokinetic/handgrip strength, body composition, resting BP/HR/SpO_2), participants return ≥96 h later for Visit-2 where they complete a 10-min warm-up (treadmill or cross-trainer, incline +5–10%) and 10-min familiarisation (four lifts at \~20% 1RM), then perform three sets of squats, standing calf raises, deadlifts, and seated leg extensions at 40%/60%/80% 1RM for 12/8/6 reps, with ~90 s between exercises and 120 s between sets, followed by cool-down stretches; allocation is non-random by disease status (ConHD vs healthy), there is no allocation concealment or blinding, and the control group consists of healthy peers undertaking the same protocol (no placebo/no-treatment arm). Outcomes include muscle strength/fatigue (pre- and \~10 min post-session), BP and PACES after each set, RPE and Feeling Scale after each exercise, continuous HR/SpO_2 throughout, and DOMS over 3-day follow-up; safety procedures include stopping if SpO_2 < 90% or a ≥3–5% fall from baseline, HR > 85% HRmax, or symptoms/arrhythmia, with AED/first-aid available on site. All procedures are conducted at the University of Exeter CHERC laboratory and St Luke's Sports Centre planned sample size is 27 ConHD + 27 healthy controls.

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Previous interventions:

This single-centre, quasi-experimental interventional study compares adolescents and young adults with congenital heart disease (ConHD) with matched healthy controls during a single supervised progressive-intensity resistance-training session: after Visit-1 screening and baseline tests (incl. CPET ramp protocol to determine HRmax, isokinetic/handgrip strength, body composition, resting BP/HR/SpO_2), participants return ≥96 h later for Visit-2 where they complete a 10-min warm-up (treadmill or cross-trainer, incline +5–10%) and 10-min familiarisation (four lifts at \~20% 1RM), then perform three sets of squats, standing calf raises, deadlifts, and seated leg extensions at 40%/60%/80% 1RM for 12/8/5 reps, with ~90 s between exercises and 120 s between sets, followed by cool-down stretches; allocation is non-random by disease status (ConHD vs healthy), there is no allocation concealment or blinding, and the control group consists of healthy peers undertaking the same protocol (no placebo/no-treatment arm). Outcomes include muscle strength/fatigue (pre- and \~10 min post-session), BP and PACES after each set, RPE and Feeling Scale after each exercise, continuous HR/SpO_2 throughout, and DOMS over 3-day follow-up; safety procedures include stopping if SpO_2 < 90%

or a ≥3–5% fall from baseline, HR > 85% HRmax, or symptoms/arrhythmia, with AED/first-aid available on site. All procedures are conducted at the University of Exeter CHERC laboratory and St Luke's Sports Centre planned sample size is 27 ConHD + 27 healthy controls.

Intervention Type
Behavioural

Primary outcome(s)
1. Peak knee extensor torque (Nm) is measured using a Biodex System 3 isokinetic dynamometer at 60°/s (mean of 3 trials) at Visit-1 baseline and Visit-2 pre-training and ~10 min post-training
2. Knee extensor fatigue index (%) is measured using a Biodex isokinetic dynamometer at 180°/s over 20 continuous maximal repetitions (fatigue index from the mean of the first 5 vs last 5 reps) at Visit-1 baseline and Visit-2 pre-training and ~10 min post-training
3. Maximal handgrip strength (N) is measured using a hand dynamometer (dominant hand, 3 trials separated by 1 min; mean of 3) at Visit-1 baseline and Visit-2 pre-training and ~10 min post-training

Key secondary outcome(s)
1. Systolic/diastolic blood pressure (mmHg) is measured using an automated sphygmomanometer (Omron M6) at Visit-1 baseline and at each set and at session end during Visit-2
2. Heart rate (bpm) is measured using a heart-rate monitor at Visit-2 before, continuously during, and after the session
3. Peripheral oxygen saturation (SpO_2, %) is measured using a fingertip pulse oximeter (Nonin Onyx Vantage) at Visit-2 before, continuously during, and after the session
4. Rating of Perceived Exertion (RPE, 0–10) is measured using the Borg CR10 scale at the rest period after each exercise during Visit-2
5. Exercise enjoyment (PACES, 4-item) is measured using the PACES questionnaire at the end of each set during Visit-2
6. Affective valence (Feeling Scale, −5 to +5) is measured using the Feeling Scale at the end of each exercise during Visit-2
7. Delayed-onset muscle soreness (DOMS, 0–10) is measured using a visual analogue scale (VAS 0–100 mm converted to 0–10) at Visit-2 pre-training (baseline) and once daily on Days 1–3 after Visit-2

Completion date
28/07/2026

Eligibility

Key inclusion criteria
For young people with ConHD:
1. Young people aged 15 to 24 years
2. People diagnosed with different types of ConHD
3. All participants with ConHD are New York Heart Association (NYHA) class I (patients will not experience discomfort in normal daily activities) to class II (patients will feel some fatigue, shortness of breath, palpitations, and other symptoms, but will not be affected during the resting state), the New York NYHA ratings for people with ConHD.

For healthy young people:
1. The age, gender, and strength training experience of the healthy participants will be matched

to those with ConHD
2. The absence of cardiovascular and respiratory diseases
3. The ability to perform moderate to vigorous activity (70% - 85% 1 RM), and adherence to verbal commands related to experimental procedures. Participants will complete a Physical Activity Readiness Questionnaire to assess their health status and exercise adaptability before the experiment

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
15 Years

Upper age limit
24 Years

Sex
All

Total final enrolment
18

Key exclusion criteria
For young people with ConHD:
1. Personal history of documented life-threatening arrhythmias
2. Inability or contraindication to perform required physical activity
3. Significant depression of left or right ventricle function (subjective or left ventricular ejection fraction < 54%)
4. Severe aortic stenosis or severe left ventricular outflow tract obstruction
5. Presence of significant non-cardiac causes that impair mobility (including respiratory, neurological, or musculoskeletal)
6. Physical inability to perform a cardiopulmonary exercise test (CPET), participation in other exercise training programmes, and contra-indications for exercise (arrhythmias)

Date of first enrolment
30/09/2025

Date of final enrolment
28/07/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The University of Exeter
St Luke's Campus, Heavitree Road, Exeter, Uk
Exeter
England
EX1 2LU

Study participating centre
UNIVERSITY HOSPITALS BRISTOL AND WESTON NHS FOUNDATION TRUST
Trust Headquarters, Marlborough St, Bristol BS1 3NU
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Sponsor information

Organisation
University of Exeter

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Not defined

Funder Name
Chinese Scholarship Council

Results and Publications

Individual participant data (IPD) sharing plan
Primary statement (public repository):
The datasets generated and/or analysed during the current study will be deposited in a public repository (Open Research Exeter, ORE) once anonymisation is complete and the thesis is

deposited. The protocol specifies that the anonymised dataset will be stored on Open Research at Exeter (ORE) alongside the published thesis.

What data will be shared (types/format):
De-identified, participant-level variables including group status (ConHD vs healthy), demographics (age, sex), CPET variables (e.g., peak VO_2, HR, GET, VE/VCO_2 slope), isokinetic knee extensor peak torque and fatigue indices, handgrip strength, blood pressure (SBP/DBP), heart rate, SpO_2, RPE (CR10), PACES, Feeling Scale, DOMS, and adverse-event/stop-criteria flags, with accompanying data dictionary/metadata.

When the data will be available and for how long:
Data will be available after study completion and anonymisation—following thesis deposit on ORE, targeted after the planned study period (01 Sep 2025–28 March 2026)—and will then be held for long-term retention (10 years after study completion) in line with the protocol's data-retention plan.

Access conditions:
Only the researcher and project supervisors have access to the working files.

Mechanism and repository details:
ORE is the University of Exeter's institutional repository; the dataset will be deposited with persistent identifiers and citation metadata. Until the ORE record is live, requests can be directed to the study coordinator (Kunyu Hao, kh704@exeter.ac.uk).

Consent, ethical and legal considerations:
All participants (and parents/guardians for 15-year-olds) provide informed consent/assent before any procedures. The protocol requires compliance with UK GDPR and University of Exeter data-protection guidance; no patient/NHS clinical data are accessed or shared by the NHS.

Anonymisation and confidentiality:
Identifiers (names, emails, phone numbers, etc.) are stored separately on password-protected, University-owned SharePoint with restricted access; after both visits and a withdrawal window, study IDs are replaced with anonymised codes before analysis, the linkage file is then destroyed, and only fully anonymised data are shared on ORE. Personal/sensitive data are retained up to one year post-closure; anonymised data are retained for 10 years after completion.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2	12/08/2026	13/08/2026	No	No