Exercise Training in Grown-Up Congenital Heart Disease.

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The objective of the study is to evaluate the effect of physical exercise on exercise capacity, quality of life and serum NT-proBNP levels in adult patients with congenital heart disease.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON46945

Source
ToetsingOnline

Brief title
The ExTra GUCH trial

Condition

- Cardiac disorders, signs and symptoms NEC
- Cardiac and vascular disorders congenital

Synonym
congenital heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Cardiologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Congenital heart disease, Exercise training, Sport

Outcome measures

Primary outcome

The primary outcome is the change in V*O2peak between patients in the sports participation group, and the control group.

Secondary outcome

Secondary outcome measures are change in NYHA functional class, quality of life, and NT-proBNP levels.

The primary safety outcome is the composite of all hospitalizations, and all deaths during, or within three hours after exercise. The secondary safety outcome is the composite of all exercise related injuries for which medical attention is sought.

Study description

Background summary

Survival of patients with congenital heart disease has steadily increased over the past decades, with even those with severe congenital cardiac anomalies currently reaching adulthood. Many patients have residual lesions of their cardiac condition, which, in addition to previous cardiac surgery and cyanosis during childhood, increases their risk to develop heart failure. In patients with acquired heart failure regular physical activity decreases both (cardiac) morbidity and mortality. Although the rationale behind the beneficial effects of physical activity seems equally applicable to grown-up congenital heart disease (GUCH) patients, no conclusive evidence exists.

Our previous, small-scaled pilot-study on exercise training in adult patients

with a systemic right ventricle demonstrated an increase in exercise capacity after a 10-week training program. In addition, exercise training was found to be safe, even in these complex cardiac patients. Indeed, it seems highly likely that exercise training will lead to substantial improvements in (cardiovascular) morbidity in a much broader spectrum of GUCH patients.

Exercise training studies in acquired heart disease showed that compliance is a pitfall. To overcome this pitfall, we hypothesized that a training program should be patient-based. More importantly, by mutual contact through social media we assume patients to remain involved and motivated. Therefore, we propose the *ExTra GUCH trial*, as a large-scale, randomized controlled trial, to evaluate the effect of sports participation on exercise capacity, morbidity and quality of life in symptomatic GUCH patients. We expect our study to provide evidence of the benefits of exercise training in GUCH patients, so to provide these young patients with the best possible cardiovascular care. In addition, the study will give insight into the expanding role of social media in cardiovascular care.

Study objective

The objective of the study is to evaluate the effect of physical exercise on exercise capacity, quality of life and serum NT-proBNP levels in adult patients with congenital heart disease.

Study design

Multi-centre, prospective, randomised trial with blinded evaluation of patient outcomes. Follow-up 26 weeks.

Intervention

The ExTra GUCH training protocol is designed to decrease participation threshold, and increase patient*s ownership. Consenting patients agree with sports participation three times per week, for 26 consecutive weeks (e.g. six months). The training schedule is set-up as follows:

Training sessions are individualized, based on the mean heart rate reserve (HRR = resting heart rate + 0.6[peak heart rate - resting heart rate]) of the HRR at latest cardiopulmonary exercise test. This ensures optimal individualized training schedules, and takes into account any possible use of medication. Each training session takes a minimum of thirty minutes. Patients are requested to keep a log for the training program, stating dates and times of performed exercise, and heart rates during exercise.

Previous exercise training studies in acquired heart disease showed that

compliance is a pitfall. To overcome this pitfall two major differences are incorporated into our study. Firstly, consenting patients can choose their sport to perform the exercise-training program as they like, as long as the above mentioned time-criteria are met.

Social media
Secondly, to increase compliance and create solidarity, consenting patients are added to the enclosed ExTra GUCH Facebook group. The ExTra GUCH Facebook group is designed to post sportive accomplishments, and study progress. Consenting patients can post questions, which can be answered by fellow participants, or the principal investigator. No clinical and/or private information is posted on the ExTra GUCH Facebook group. The principal investigator manages the ExTra GUCH Facebook group. Participation in the ExTra GUCH Facebook group is voluntary, and refusal to participate does not exclude consenting patients from participation in the trial.

Patients can cease the exercise training at any time and for any reason without consequences for the patient*s further treatment.

Study burden and risks

Previous studies on exercise in adult patients with congenital heart disease showed exercise to be safe in this patient population. Exercise related injuries are to be expected. Although no (major) cardiovascular events are expected from the proposed study, all events will be noted.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age >= 18 years
Congenital heart disease
NYHA Class II or III

Exclusion criteria

Inability to give informed consent
Inability to participate in an exercise training program
Exercise-induced arrhythmia and/or ischemia
Cyanosis at rest
Pregnancy
Major cardiovascular event and/or procedure within three months previous to inclusion.
Participation in interventional clinical trial

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-01-2016
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	21-10-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL53782.018.15