

# High intensity interval training in patients with tetralogy of Fallot

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON29511

### Source

NTR

### Brief title

TOFHIIT

### Health condition

Tetralogy of Fallot

## Sponsors and support

**Primary sponsor:** Erasmus MC

**Source(s) of monetary or material Support:** Nederlandse Hartstichting & Stichting Hartekind

## Intervention

## Outcome measures

### Primary outcome

Decrease in pulse wave velocity in the aorta and pulmonary artery measured by MRI.

### Secondary outcome

Exercise capacity measured with a cardiopulmonary exercise test (VO<sub>2</sub> peak and Wattage peak)

2. Other measures of cardiac function:

\* MRI: Left and right end diastolic, end systolic, stroke volume and ejection fraction. Changes in wave reflection patterns in the pulmonary artery following the method described by Schafer et al.(11) Mass and thickness of the ventricle wall. Flow variables in the aorta and pulmonary arteries not covered by our main endpoint including 4D flow analysis.

Patient data can be compared to existing local reference data of healthy volunteers

\* Echo: Two-dimensional echocardiography An echocardiogram will be made by a trained sonographer or pediatric cardiologist on a commercially available ultrasound platform. Echocardiography will be used to assess the following variables of cardiac size and function:  
Global ventricular function (ventricular volumes, ejection fraction)  
Regional ventricular function: right and/or left ventricular or single ventricular global and regional strain / strain rate. Diastolic ventricular function: peak velocity of the antegrade systolic wave, early diastolic wave and the peak velocity of the late diastolic retrograde wave will be measured of the pulmonary venous flow E and A velocities, and E - A ratio will be assessed of systemic atrioventricular flows. Semiquantitative assessment of semilunar and atrioventricular valve regurgitation. Patient data can be compared to existing local reference data of healthy volunteers.

3. Changes in height, weight and body fat percentage and their derivatives BMI and BSA

4. Questionnaires of quality of life (QoL)

\* Will be assessed using CHQ-PF28, CHQ-CF45 (for participants under 18), SF36 (for participants over 18) and SQUASH

## Study description

### Background summary

Rationale: Tetralogy of Fallot is the most common type of cyanotic congenital heart disease. The main problems of this patient population are heart failure related to chronic pulmonary regurgitation, arrhythmias and sudden cardiac death. A major gap in our knowledge is how coupling between the RV and pulmonary artery affects outcomes. A promising method to investigate RV-PA coupling is by looking at pulse wave velocity and wave reflection patterns in the main pulmonary artery and proximal branches non-invasively. It has been shown that left sided pulse wave velocity can be improved by exercise training in Tetralogy of Fallot by exercise training.

Objective: Primary Objective: To examine the effect of an online based exercise training protocol on ventriculo-arterial coupling, as assessed by pulse wave velocity in the aorta and

pulmonary artery in patients operated for Tetralogy of Fallot.

Secondary Objective(s): To examine the effect of an online based exercise training protocol on the increase in exercise capacity and quality of life in patients with Tetralogy of Fallot.

Study design: The design of our study is a cross-over interventional study. All children and young adults will be randomized in 2 groups. One group will start with care/exercise as usual, the other group will start with an online exercise training. After 12 weeks the groups will change from protocol. Before start of measurements, after 12 weeks and group 2 after 24 weeks, all participants will undergo a number of tests, including echocardiogram, cardiopulmonary exercise test, and cardiac magnetic resonance imaging.

Study population: 12-30 years of age, after surgical repair of tetralogy of Fallot (TOF), being followed at one of the 2 locations of the Academic Center for Congenital Heart disease (ACAHA) (Erasmus MC, Sophia children's hospital, Radboud UMC Amalia children's hospital).

Intervention (if applicable): 12 weeks of online based interval training 3 times a week.

Main study parameters/endpoints: Decrease in pulse wave velocity in the aorta and pulmonary artery measured by MRI.

## **Study objective**

HIIT can lower PWV in the Aorta and pulmonary Artery in patients with Tetralogy of Fallot

## **Study design**

Group A

Baseline (week 0)

After exercise program (week 12)

Group B

Baseline (week 0)

After control period (week 12)

After exercise program (week 24)

## **Intervention**

Trainings intervention:

Due to the ongoing COVID-19 pandemic we prefer an online intervention (example shown at: <https://pedcardio.shinyapps.io/TOFHIIT-example/>), in this pandemic it is not clear if/when gyms and physiotherapists will be available. One training a week consists of jump roping (training 1), one training are body weight exercises (training 2) and the last training is one of the choosing of the participants such as running or bike riding (training 3). All trainings are approximately 30 minutes in length Training 1 and 2 will be monitored in a MS teams session and via heart rate monitor (HRM), training 3 can be done at a time of the choosing of the participant and the heart rate monitoring file will be sent to the researcher. Training 1 and 3 will be done using the 10-20-30 HIIT protocol which has been shown to be more effective compared to continues moderate intensity training. This protocol can be used in different

activities in short it consists of 10 seconds of high intensity followed by 20 seconds of moderate intensity followed by 30 seconds of very light intensity.

## Contacts

### **Public**

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### **Scientific**

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## Eligibility criteria

### **Inclusion criteria**

- \* Surgical repair for Tetralogy of Fallot through transatrial-transpulmonary repair, below the age of 2 years.
- \* Between 12 and 30 years of age
- \* Being followed in Erasmus MC, Sophia Childrens hospital, Radboud UMC, Amalia children's hospital
- \* Does not comply with the "Nederlandse Norm Gezond Bewegen"

### **Exclusion criteria**

- \* Inability to exercise or a contraindication for exercise such as long QT syndrome
- \* Contra indication for MRI such as a non MRI compatible pacemaker
- \* Ventricular outflow obstruction higher than 36 mmHg
- \* Developmental delay
- \* History of pulmonary valve replacement
- \* Use of beta blockers
- \* Documented cardiac arrhythmias

## Study design

### Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-10-2021
Enrollment:	44
Type:	Anticipated

### IPD sharing statement

**Plan to share IPD:** No

## Ethics review

Positive opinion	
Date:	27-09-2021
Application type:	First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 51183  
Bron: ToetsingOnline  
Titel:

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

No registrations found.

## In other registers

Register	ID
NTR-new	NL9754
CCMO	NL76553.078.21
OMON	NL-OMON51183

## Study results