# Stress reduction by respiratory bio feedback training as an additional rehabilitation method after acute myocardinal infarction.

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The objective of the study is to investigate if respiratory feedback training as an additional rehabilitation method after acute myocardial infarction might improve quality of live Primary objective: Is quality of live as measured by the "Heart...

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Coronary artery disorders |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON35684

**Source**
ToetsingOnline

**Brief title**
Respiratory bio feedback training after myocardial infarction.

### Condition

- Coronary artery disorders
- Anxiety disorders and symptoms

**Synonym**
cardiac rehabilitation after myocardial infarct

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud
**Source(s) of monetary or material Support:** Ministerie van OC&W,Q-Vive

## Intervention

**Keyword:** biofeedback, cardiac revalidation, stress, stress reduction

## Outcome measures

### Primary outcome

The sumscore of the Spielburger state-trait anxiety inventory (STAI)

### Secondary outcome

Time domain parameters for heart rate variability.

Mean heart rate (beats/min)

Mean RR tijdintervals (ms)

Standard deviation RR intervals (ms)

Standaard deviation of successive RR interval differences, RMSSD (ms).

Number of successive intervals differing more than 50 ms express as an

percentage (pNN50).

Frequency domain parameters for heart rate variability.

Integrated power in the low frequency (LF) band (0.04 -0.15 Hz).

Integrated power in the high frequency (HF) band (0.15 - 0.4 Hz).

The ratio between Lf an HF band powers powers (L/H ratio).

# Study description

**Background summary**

Respiratory bio feedback training as an additional rehabilitation method for patients after an acute ST elevated myocardial infarction with primary coronair intervention in the acute phase.

Mental stress is common in patients with coronary heart disease and is a risk factor for cardiac morbidity and mortality. Depression is associated with autonomic nervous system dysfunction, which may at least partially explain this increased risk (1).

The autonomuc nervous system activity is increased after myocard infarction characterized by sympathetic hyperactivity and reduced vagal activity (2.3,4). Biofeedback is a self-regulating therapy in which the patient can influence the activity of its own autonomic nervous system. Up to the fifties scientists believed that autonomic funtions such as digestion, blood pressure, and body temperature could not be self controled. However, after the fifties it became clear that
the input of the autonomic nervous system can be regulated by mindfulness and training (5). Heart rate variability describes the variations between consecutive heartbeats and can be used to reflect sympatho-vagal balance. This non invasive measurement of the autonomic nervous activity gives information about vagal modulation and symphatovagal interaction. In particular HRV depends on extrinsic heart rate regulation and reflects the ability of the heart to adapt fast to non-predictable circumstances (6). Reduced heart rate variability is associated with poor prognostics after myocardial infarction (3,6). Heart rate variability can be increased by respiratory biofeedback training (5). Only little is known about the effect size of respiratory feedback training in patients with acute myocardial infarct and PCI.QT Interval variability will be determined during exercise as a measure of autonomic activity.

The objective of the study is to investigate the use of respiratory feedback training as a means of stress management to improve prognosis after an acute ST elevated myocardinal infarction with primary coronair intervention in the acute phase.

Literature
1)
R.M. Carney, K.E. Freeland. Depression and heart rate variability in patients with coronary heart disease, Cleveland Clinic Journal of Medicine (2009) 76:S13-17.
2)
G. R. H. Sandercock, R. Grocott-Mason, D. A. Brodie, Changes in short-term measures of heart rate variability after eight weeks of cardiac rehabilitation, Clin Auton Res (2007) 17:39-45.
3)
M. Quintana, N. Storckf, L. E. Lindbladf, K. Lindvall and M. Ericson, Heart rate variability as a means of assessing prognosis after acute myocardial infarction, a 3-year follow-up study, European Heart Journal (1997) 18, 789-797.
4)
Balanescu S, Corlan A, Dorobantu M, Gherasim L (2004) Prognostic value of heart rate variability after acute myocardial infaction. Med Sci Monit, 10:CR307-CR315.
5)
C. S. Moravec, Biofeedback therapy in cardiovascular disease: Rationale and research overview, Cleveland Clinic Journal Of Medicine (2008) 75 S35-S38.
6)
U. R. Acharya, K. P. Joseph , N. Kannathal, C. Min Lim, J. S. Suri, Heart rate variability: a review, Med Bio Eng Comput (2006) 44:1031-1051.
7)
N. Singh, D. Mironov, P.W. Armstrong, A. M. Ross, A. Langer,for the GUSTO ECG Substudy Investigators, Heart Rate Variability Assessment Early After Acute Myocardial Infarction, Circulation. 1996;93:1388-1395.

**Study objective**

The objective of the study is to investigate if respiratory feedback training as an additional rehabilitation method after acute myocardial infarction might improve quality of live

Primary objective:

Is quality of live as measured by the "Heart Patients Psychological Questionaire (HPPQ) at the end of rehabilitation and one year after myocardial infarction and Percutaneous Coronary Intervention (PCI) more improved in the intervention group compared to the non intervantion group.

secondarily objective:

Are heart rate variability parameters in the intervention- and non intervention group different from each other at the end of the rehabilitation period and

one year after myocardial infarction.

### Study design

Prospective randomized case control trial matched for gender and age.

### Study burden and risks

The burden for the intervention group is 30 minutes coaching a week and 5 minutes daily training. It is anticipated that coaching and training will be appreciated. If not the patient is free to end the program any time he or she would like to be. The burden for both the intervention and non-intervention group is to fill in the STAI questionnaire at intake and after one year. It is considered that the program is free of any risk.

## 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

Patients with ST elavated myocardial infarct treated with primary PTCA in the acute phase.
age 40-70 years old
good Dutch understanding and writing

### Exclusion criteria

Patients who do not participate in the standard revalidation program.
younger than 40 years
older than 70 years
patients unable to speak or write Dutch

## Study design

### Design

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| Study type: | Observational non invasive |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Prevention

### Recruitment

NL

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| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-07-2010 |
| Enrollment: | 56 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 23-03-2010 |

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| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

# 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 | NL28092.091.09 |