MOVE-CRT: A study to describe physical activity in heart failure patients with cardiac resynchronization therapy (CRT)

Published: 05-07-2023
Last updated: 30-01-2025

To describe physical activity level before and after CRT implantation and to explore factors related to the intention of patients with HF for implementing behaviour change (improve activity level). We want to collect this data to plan future...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON53635

Source
ToetsingOnline

Brief title
MOVE-CRT

Condition

- Heart failures

Synonym
Heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiac Resynchronization Therapy, Physical activity

Outcome measures

Primary outcome

• Daily physical activity

• Self-reported activity level

Secondary outcome

• Submaximal Exercise Capacity

• Exercise Motivation

• Health related Quality of life and well-being.

• Anxiety and depression

• LV volumes and function measured by echocardiography

• NT-proBNP levels

• Number of missing questionnaires at T0, T1, T2 and T3

Study description

Background summary

Physical activity, including regular exercise, is important for patients with heart failure (HF). One might expect that after a CRT implantation, patients are in a better shape to more active and will be able to change their physical activity. However, it is known that more is needed to change behaviour, for example to being motivated and feeling empowered to be more active. An intervention at home using eHealth seems promising to improve physical activity. However, to design an eHealth intervention for this patient group, more information is needed on their actual activity level, their motivation and barriers for physical activity and the perceived role of patients themselves.

Study objective

To describe physical activity level before and after CRT implantation and to explore factors related to the intention of patients with HF for implementing behaviour change (improve activity level). We want to collect this data to plan future research. We also collect data on the feasibility of such a study. The long term goal is to develop an eHealth intervention.

Study design

This study is a descriptive longitudinal pilot study with 12 months follow-up.

Study procedures

Baseline visit: about 2 months before CRT implantation
- Demographic and clinical data are collected from the electronic health record;
- Respondent complete digital questionnaires at home;
- Combined with the regular outpatient visit, a research nurse administers the 6-minute walk test and the respondent is instructed on the activity meter and receives it to wear for 2 weeks (excluding at night).

Follow up visits: About 2 and 6 months after CRT implantation
- Demographic and clinical data are collected from the electronic health record
- Respondents complete digital questionnaires at home
- Combined with the regular outpatient visit, a research nurse administers the 6-minute walk test and the respondent is instructed on the activity meter and receives it to wear for 2 weeks (excluding at night).

Follow up visit: about 12 months
- Demographic and clinical data are collected from the electronic health record
- Respondents complete digital questionnaires at home

Study burden and risks

No medical intervention is performed in the context of this study. The burden consists of completing questionnaires 4 times (30 minutes each time), doing a 6-minute walk test 3 times and wearing an activity monitor 3 times for 2 weeks in 12 months. Since we collect data during scheduled visits, no additional outpatient clinic visits are required and we believe our study is safe.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100

Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Diagnosis of chronic heart failure according to the prevailing guidelines
- Elective first-time implantation of CRT (pacemaker (CRT-P) or defibrillator (CRT-D)) in UMCU
- Adult (age >= 18 years)

Exclusion criteria

- Scheduled cardiac surgery within 3 months
- Problems to fill in questionnaires
- Problems to wear an activity monitor
- Previously implanted pacemaker or defibrillator device
- On an active waiting list for left ventricular assist device (LVAD) implantation or heart transplantation
- Inability to provide informed consent

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-01-2024
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	05-07-2023
Application type:	First submission
Review commission:	METC NedMec

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	NL80692.041.23