

# Remote monitoring in heart failure patients

<b>Submission date</b> 23/06/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 27/06/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/06/2017	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Chronic heart failure (CHF) is a long-term condition where the heart has become weakened and isn't able to pump blood around the body effectively. It is very common, meaning that related hospital admissions and healthcare costs continue to rise. With the ageing population and improving treatment of coronary artery disease (blockage of the main heart arteries), the incidence of heart failure will continue to increase rapidly. Many patients with heart failure now have implantable devices to help manage their condition. The purpose of this study is to help to understand how to better use the information from these devices, in order to prevent death or admission to hospital, and to improve health-related quality of life. Until recently all patients who have a pacemaker (a device which uses electrical pulses to maintain a normal heart rhythm) or defibrillator (a device which shocks the heart into a normal rhythm) fitted have been required to attend routine clinic appointments in hospital to have their device readings checked. Because of advances in technology, some devices now allow physicians to retrieve that information without the need for patients to attend device clinics. Patients with these devices can now transmit their device data from the comfort of their own home. This is done with a small monitor that is used to send device data over a telephone line to a secure server. Clinical staff then access and review the device data remotely. The aim of this study is to see how best hospital study teams can manage patients care using these advances in technology.

### Who can participate?

Adults with heart failure who have had an implantable device for at least six months that is suitable for remote monitoring.

### What does the study involve?

Patients with devices are randomly allocated to one of two groups. Those in the first group are monitored using remote management technology for heart failure assessment using specific care guidelines. This involves being invited to have their device checked weekly from home over the internet. Those in the second group follow their local hospital routine standard of care which may involve some remote follow up and/or attending hospital device clinics (generally every three to six months). Participants in both groups are contacted by telephone after three, six and twelve months and then yearly until the end of the study (minimum of two years) to ask about their progress. All participants also complete a number of questionnaires to return by post at these times to assess their quality of life.

What are the possible benefits and risks of participating?

There are no known benefits or risks involved with participating in this study.

Where is the study run from?

Southampton General Hospital (lead centre) and eight other NHS hospitals in England (UK)

When is the study starting and how long is it expected to run for?

September 2011 to January 2016

Who is funding the study?

1. British Heart Foundation (UK)
2. Boston Scientific Ltd (UK)
3. Medtronic Ltd (UK)
4. St Jude Medical Ltd (UK)

Who is the main contact?

1. Mrs Sue Kitt (public)  
sue.kitt@uhs.nhs.uk
2. Professor Martin Cowie (scientific)  
m.cowie@imperial.ac.uk

## Contact information

### Type(s)

Public

### Contact name

Mrs Sue Kitt

### ORCID ID

<http://orcid.org/0000-0001-6051-4810>

### Contact details

University Hospitals Southampton NHS Foundation Trust  
Southampton  
United Kingdom  
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### Type(s)

Scientific

### Contact name

Prof Martin Cowie

### ORCID ID

<http://orcid.org/0000-0001-7457-2552>

### Contact details

Royal Brompton Hospital  
Sydney Street  
London  
United Kingdom  
SW3 6NP  
+44 (0)207 351 8856  
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## **Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

UKCRN10383

## **Study information**

**Scientific Title**

REmote Monitoring and evaluation of implantable devices for management of Heart Failure patients

**Acronym**

REM-HF

**Study objectives**

The aim of this study is to assess whether patient-independent remote monitoring using implanted device technology and deployed in clinical pathways designed for chronic management of heart failure in the home will significantly reduce all-cause patient mortality and cardiovascular hospitalisation in the context of NHS care and will be more cost effective than usual care.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

NRES Committee Yorkshire and The Humber- Sheffield, 17/05/2011, ref: 11/YH/0062

**Study design**

Multicentre randomised non-blinded interventional controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

**Health condition(s) or problem(s) studied**

Heart failure

**Interventions**

Participants are randomised to one of two groups.

Group 1: Participants will be set up with remote device monitoring and arrangements made for a weekly device download to be transmitted to their local study hospital. Some participants may already use remote monitoring but this will be on a much less frequent basis, usually 3 to 6 monthly. The weekly downloads will be reviewed by the nurse or cardiac technician who are the "trained study remote monitor". The monitor will review the weekly downloads and take any appropriate actions which are then documented as part of the study data.

Group 2: Participants will have their device care managed according to the usual care in their local hospital.

Both groups will be contacted by telephone at 3, 6, 12 month and yearly following enrolment to ask about their progress. Data regarding their progress will be collected from the telephone follow up and supported by hospital and GP medical records. All participants will be required to complete "Quality of Life" (QOL) questionnaires at baseline, 3, 6, 12 and 24 months following enrolment. The latter 4 QOL questionnaires may be sent in the post. Depending on the date of their enrolment each participant will be followed up in the study for up to 4 years with a minimum of 2 years follow up.

**Intervention Type**

Device

**Primary outcome measure**

Combined all-cause mortality (ACM) or unplanned cardiovascular (CV) hospitalisation (whichever comes first) rate is determined through follow up interviews at 3, 6, 12 month, 2 years and for the early recruiters up to 4 years. Data will be collected from a combination of participant interviews, reviewing hospital and GP records and by obtaining copies of death certificates where available from the Health and Social Care Information Centre.

**Secondary outcome measures**

Unless otherwise stated, secondary outcome measures will be measured at the last follow-up or at the last available observation within the two year follow-up period.

1. Time to death is measured by time from randomisation to date of death
2. Time to a cardiovascular related death is measured by time from randomisation to date of death

3. Time to a non-cardiovascular related death is measured by time from randomisation to date of death
4. Time to first unplanned hospitalisation for cardiovascular reasons or cardiovascular related death is measured by time from randomisation to date of event
5. Time to first unplanned hospitalisation for non-cardiovascular reasons or death by any cause is measured by time from randomisation to date of event
6. Time to first unplanned hospitalisation for cardiovascular reasons is measured by time from randomisation to date of event
7. Time to first unplanned hospitalisation for non-cardiovascular reasons is measured by time from randomisation to date of event
8. Total number of unplanned hospitalisations is measured by the total number of these episodes during the follow up period
9. Total number of unplanned hospitalisations for cardiovascular reasons is measured by the total number of these episodes during the follow-up period
10. Health related quality of life is measured using the SF12 (physical and mental health components) at baseline, 3 month, 6 month, 12 month, 1 and 2 years
11. Health related quality of life is measured using the EQ5D at baseline, 3 month, 6 month, 12 month, 1 and 2 years
12. Health related quality of life is measured using the KCCQ at baseline, 3 month, 6 month, 12 month, 1 and 2 years
13. Number and cost of hospitalisations is measured by applying the national tariff costs to the hospitalisation episodes
14. Difference in cost of resources consumed is measured by applying appropriate costs to both arms of the studies and comparing these for the duration of the study
15. Difference in cost of cardiovascular related health care use is measured by applying the appropriate costs to both arms of the studies and comparing these for the duration of the study
16. Incremental costs per quality-adjusted life years (QALYs) is measured by dividing the difference in costs between both arms of the study by the difference in QALYs between the arms

### **Overall study start date**

01/01/2010

### **Completion date**

31/01/2016

## **Eligibility**

### **Key inclusion criteria**

1. Participants will all have received an Implantable Cardioverter Defibrillator (ICD), Cardiac Resynchronisation Therapy-Pacemaker (CRT-P) or Cardiac Resynchronisation Therapy-Defibrillator (CRT-D) at least six months previously, for the treatment and monitoring of chronic heart failure
2. Be on stable medical therapy for CHF for 6 weeks prior to recruitment
3. Will have the ability to independently comprehend and complete Quality of Life Questionnaires
4. Will have the ability to give informed consent
5. Will be on optimal medical therapy according to the treating physician, working to NICE Guidelines
6. Will have had their device programmed to give optimal therapy according to the treating physician
7. Will have symptomatic heart failure (i.e. NYHA Class II to IV) documented at the time of study

enrolment

8. Will be at least 30 days post any device change or lead replacement procedure

9. Will be at least 3 months post any cardiac surgical procedure

10. Will be at least 3 months post acute myocardial infarction

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

1650

**Key exclusion criteria**

1. Unable to use the technology due to mental or physical limitations

2. Less than 18 years old

3. Pregnancy

4. On a heart transplant list

5. Life expectancy of < one year (non cardiovascular related) in the opinion of the treating physician

6. Current device related complications, e.g. wound infection or haematoma, lead fracture

7. Device implanted less than 6 months previously

8. Patients unable to understand written and spoken English.

**Date of first enrolment**

29/09/2011

**Date of final enrolment**

31/03/2014

**Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Southampton General Hospital**

University Hospital Southampton NHS Foundation Trust

Tremona Road

Southampton

United Kingdom

SO16 6YD

**Study participating centre**

**Royal Brompton Hospital**

Royal Brompton and Harefield NHS Foundation Trust  
Sydney Street  
London  
United Kingdom  
SW3 6NP

**Study participating centre**

**Blackpool Victoria Hospital**

Blackpool Teaching Hospitals NHS Foundation Trust  
Whinney Heys Road  
Blackpool  
United Kingdom  
FY3 8NR

**Study participating centre**

**St Thomas' Hospital**

Guys and St Thomas' Hospital NHS Foundation Trust  
Westminster Bridge Road  
London  
United Kingdom  
SE1 7EH

**Study participating centre**

**Leeds General Infirmary**

Leeds Teaching Hospital NHS Trust  
Great George Street  
Leeds  
United Kingdom  
LS1 3EX

**Study participating centre**

**Glenfield Hospital**

University Hospitals of Leicester NHS Trust  
Grobby Road  
Leicester  
United Kingdom  
LE3 9QP

**Study participating centre****Liverpool Heart and Chest Hospital**

Liverpool Heart and Chest Hospital NHS Foundation Trust  
Thomas Drive  
Liverpool  
United Kingdom  
L14 3PE

**Study participating centre****Wythenshawe Hospital**

University Hospital of South Manchester NHS Foundation Trust  
Southmoor Road  
Wythenshawe  
Manchester  
United Kingdom  
M23 9LT

**Study participating centre****Freeman Hospital**

Newcastle Hospitals NHS Foundation Trust  
Freeman Road  
High Heaton  
Newcastle upon Tyne  
United Kingdom  
NE7 7DN

## **Sponsor information**

**Organisation**

University Hospital Southampton NHS Foundation Trust

**Sponsor details**

Tremona Road  
Southampton  
England  
United Kingdom  
SO16 6YD

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/0485axj58>



# Funder(s)

## Funder type

Charity

## Funder Name

British Heart Foundation

## Alternative Name(s)

the\_bhf, The British Heart Foundation, BHF

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Trusts, charities, foundations (both public and private)

## Location

United Kingdom

## Funder Name

Boston Scientific Corporation

## Alternative Name(s)

Boston Scientific, Boston Scientific Corp., BSC

## Funding Body Type

Government organisation

## Funding Body Subtype

For-profit companies (industry)

## Location

United States of America

## Funder Name

Medtronic

## Alternative Name(s)

Medtronic Inc.

## Funding Body Type

Private sector organisation

### **Funding Body Subtype**

For-profit companies (industry)

### **Location**

United States of America

### **Funder Name**

St. Jude Medical

### **Alternative Name(s)**

St. Jude Medical, Inc., SJM

### **Funding Body Type**

Private sector organisation

### **Funding Body Subtype**

For-profit companies (industry)

### **Location**

United States of America

## **Results and Publications**

### **Publication and dissemination plan**

1. Study results will published in peer reviewed scientific journals once the data analysis is complete
2. Results will additionally be presented at scientific meetings and use our contacts with the British Heart Foundation medical charity to disseminate the results to a wider audience

### **Intention to publish date**

03/09/2016

### **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Data sharing statement to be made available at a later date

### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	01/09/2014		Yes	No
<a href="#">Results article</a>	results	07/08/2017		Yes	No