# Home monitoring with integrated risk-stratified disease management support versus home monitoring alone in patients with heart failure

Submission date 05/09/2014	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
		[_] Protocol		
Registration dateOverall study state05/09/2014Completed	Overall study status	[] Statistical analysis plan		
	Completed	[X] Results		
Last Edited 16/06/2021	Condition category Circulatory System	[_] Individual participant data		

# Plain English summary of protocol

Background and study aims

In this study the aim is to test whether a mobile health home monitoring system, which is linked to patients health records and able to provide specialist alert and advice to patients and predictive clinical decision support tools to healthcare practitioners, can improve heart failure patients management.

Who can participate? Adult men and women diagnosed with heart failure

### What does the study involve?

Participants are randomly allocated to either receive personalised feedback on their health or not. Participants are given and taught how to use a tablet PC to answer a short series of questions about their health and wellbeing and record their blood pressure, weight and heart rate. They are asked to complete these questions and measurements on a daily or regular basis for a period of about 6 months. Some participants may also be asked to carry a small monitor (FitBit) to record information about their level of physical activity and sleeping pattern. All of this data is captured and stored securely on the tablet PC and then wirelessly transferred in realtime to secure central servers at the University of Oxford where it is reviewed by researchers. Depending on treatment allocation and participants health monitoring data, they may receive more or less intensive feedback to support themselves in managing their condition better at home.

What are the possible benefits and risks of participating?

It is hoped that everyone taking part will improve their knowledge and understanding of managing heart failure. In addition, it is hoped that the intervention will improve partcipants' medication management and quality of life. However, this cannot be guaranteed. The information gained from this study may help to treat patients with heart failure better in the future. There are no expected harms from participating in this study. Where is the study run from? The study is run from the participants' homes

When is the study starting and how long is it expected to run for? September 2014 to September 2017

Who is funding the study? 1. National Institute for Health Research (NIHR) Oxford Biomedical Research Centre 2. National Institute for Health Research (NIHR) Career Development Fellowship

Who is the main contact? Prof. Kazem Rahimi kazem.rahimi@wrh.ox.ac.uk

Study website http://supporthf.org/

# **Contact information**

**Type(s)** Scientific

**Contact name** Prof Kazem Rahimi

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# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers** 17276

# Study information

### Scientific Title

Home monitoring with integrated risk-stratified disease management support versus home monitoring alone in patients with heart failure: a randomised controlled trial

Acronym

SUPPORT-HF 2

### **Study objectives**

In patients with heart failure, home monitoring coupled with an integrated data analysis and risk prediction service, providing real-time alerts and advice to patients and predictive clinical decision support tools to healthcare practitioners, is more effective in optimising medical therapy than home monitoring with the same monitoring equipment but without the use of the integrated data analysis and decision support service and the tailored self-management tools.

### Ethics approval required

Old ethics approval format

**Ethics approval(s)** First MREC approval date 28/08/2014, ref: 14/SS/1025

**Study design** Randomised; Interventional; Design type: Prevention

**Primary study design** Interventional

Secondary study design Randomised controlled trial

**Study setting(s)** Home

**Study type(s)** Prevention

### 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

Topic: Cardiovascular disease; Subtopic: Cardiovascular (all Subtopics); Disease: Heart Failure

### Interventions

Intervention: Collection of symptoms, physiological and system usage information from commercially available home monitoring devices and their integration with electronic health records (EHRs) for estimation of fluid status and risk. Risk-based algorithmic management supported by a specialist medical team and computer algorithms.

Control: Collection of symptoms, physiological and system usage information from commercially available home monitoring devices, as well as biochemical data from EHRs, but the data

collected will not processed to provide personalised feedback to patients for self-management or to their doctors for risk-based monitoring or drug management. Participants pharmacological care will not be supported by the system.

### Intervention Type

Other

**Phase** Not Applicable

### Primary outcome measure

Optimal medical therapy is defined as treatment consistent with the NICE guidelines for management of patients with chronic heart failure and will be measured as a composite opportunity score

## Secondary outcome measures

Not provided at time of registration

# Overall study start date

01/09/2014

# **Completion date**

30/09/2017

# Eligibility

# Key inclusion criteria

1. Participant is willing and able to give informed consent for participation in the trial

2. Male or female, aged 18 years or above

3. Diagnosed with heart failure, defined as presence of typical symptoms (e.g. breathlessness, ankle swelling, and fatigue) and signs (e.g. elevated jugular venous pressure, pulmonary crackles, and displaced apex beat) resulting from an abnormality of cardiac structure or function

4. Potential to benefit from home monitoring and management defined as:

4.1. Self-assessed NYHA class II to IV; or

4.2. BNP >100 pg/L or NT-pro-BNP >360 pg/L in the last 30 days (excluding in-hospital measures) AND either

4.3. Not on optimal therapy (in view of the Investigator), or

- 4.4. Probability of death within one year >10% (MAGGIC integer score 20 or more)
- 4.5. At least one hospital admission related to heart failure in the previous 12 months

# Participant type(s)

Patient

Age group

Adult

**Lower age limit** 18 Years Both

**Target number of participants** Planned Sample Size: 200; UK Sample Size: 200

Total final enrolment

202

# Key exclusion criteria

1. No reliable 3G mobile or Wi-Fi network connectivity at home

2. Unable to read or speak English

3. Any other significant disease, including critical unstable or end-stage heart failure, which, in the opinion of the Investigator, may either put the participants at risk because of participation in the trial, or may influence the result of the trial, or the participants ability to participate in the trial

Date of first enrolment

01/09/2014

# Date of final enrolment 30/06/2017

# Locations

**Countries of recruitment** England

Northern Ireland

United Kingdom

**Study participating centre Oxford University Hospitals NHS Foundation Trust** Oxford United Kingdom OX3 9DU

**Study participating centre Frimley Health NHS Foundation Trust** Camberley United Kingdom GU16 7UJ

Study participating centre

#### **Milton Keynes University Hospital NHS Foundation Trust** Milton Keynes United Kingdom MK6 5LD

**Study participating centre Leicestershire Partnership NHS Trust** Leicester United Kingdom LE4 8PQ

**Study participating centre Royal Devon and Exeter NHS Foundation Trust** Exeter United Kingdom EX2 5DW

**Study participating centre Central Manchester University Hospitals NHS Foundation Trust** Manchester United Kingdom M13 9WL

**Study participating centre South Eastern Health and Social Care Trust** Dundonald United Kingdom BT16 1RH

# Sponsor information

**Organisation** University of Oxford (UK)

**Sponsor details** Clinical Trials & Research Governance Research Services Joint Research Office Block 60 Churchill Hospital Oxford England United Kingdom OX3 7LE

**Sponsor type** University/education

ROR https://ror.org/052gg0110

Funder(s)

**Funder type** Government

### Funder Name

NIHR Career Development Fellowship (UK); Grant Codes: CDF-2013-06-012

**Funder Name** NIHR Oxford Biomedical Research Centre (BRC)

# **Results and Publications**

### Publication and dissemination plan

The trialists intend to publish the baseline findings before the completion of the trial and then the final results, both in speciality cardiology journals.

### Intention to publish date

31/01/2020

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study may be available upon request from supporthf@georgeinstitute.ox.ac.uk

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	design and baseline results	01/02/2019		Yes	No
<u>Results article</u>	results	01/10/2020	08/07/2020	Yes	No

Other publications	report	27/10/2020	29/10/2020	Yes	No
HRA research summary			26/07/2023	No	No