

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

Submission date 05/09/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/09/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/06/2021	Condition category Circulatory System	<input type="checkbox"/> 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 real-time 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 participants' 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

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Prevention

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 be 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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Northern Ireland

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)

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

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
Results article	results	01/10/2020	08/07/2020	Yes	No
HRA research summary			26/07/2023	No	No
Other publications	report	27/10/2020	29/10/2020	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes