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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

Registration date
05/09/2014

Overall study status
Completed

Last Edited
16/06/2021

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 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
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Study website
http://supporthf.org/

Contact information

Type(s)
Scientific

Contact name
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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

Sex

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
Results article	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